CLINICAL STUDY REPORT

1. Title Page

Study Title: A double blind, placebo controlled, three arm, randomized clinical trial to evaluate the immuno boosting activity and to assess the efficacy and safety of the test products DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) Mfd. By LIFECARE NEURO PRODUCTS LTD, Himachal Pradesh (India) along with Standard of Care in novel corona virus (COVID-19) patients.

Protocol No.	PHAR/LNPL/COVID19/2020/04
Version Date	01 dated 26 Nov 2020
Investigational Products	DailyTab™ Gold (Immuno Booster) DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)
Name & Address of Sponsor	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Name & Affiliation of the Principal Investigator	Dr. Giriraja K V Consultant- General Medicine Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India.
Study Initiation Date (First subject in)	06 Jan 2021
Study Completion Date (Last subject out)	01 Mar 2021
No. of patients	45
Duration of treatment	28 Days
Report Number	PHAR/LNP/COVID19/2021/REPORT/01
Date of the Report	12 March 2021

INVESTIGATOR(S) SIGNATURE(S)

A Clinical study titled: A double blind, placebo controlled, three arm, randomized clinical trial to evaluate the immuno boosting activity and to assess the efficacy and safety of the test products DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) Mfd. By LIFE CARE NEURO PRODUCTS LTD, Himachal Pradesh (India) along with Standard of Care in novel corona virus (COVID-19) patients.

I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

NAME AND ADDRESS	Role	Signature & Date
Dr.Giriraja K V MBBS, MD Consultant- General Medicine Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India	Principal Investigator	SIGN & DATE: K.V. giriraja 12/03/2021 SEAL: RAJALAKSHMI HOSPITAL # 21/1, Lakshmipura Main Road (Opp. Abbigere Lake), Vidyaranyapura PO BANGALORE-560 097 Phone 080-2325 4855 / 2325 4856

3. STATEMENT OF COMPLAINCE

A Clinical study titled: "A double blind, placebo controlled, three arm, randomized clinical trial to evaluate the immuno boosting activity and to assess the efficacy and safety of the test products DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) Mfd. By LIFECARE NEURO PRODUCTS LTD, Himachal Pradesh (India) along with Standard of Care in novel corona virus (COVID-19) patients."

This study was conducted in compliance with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Role	Name	Signature & Seal	Date (DD MMM YYYY)
CRO	Baburao Vikram M.S. Pharm. Director Pharexcel Consulting 11, 10th Cross, AYR lay out, ShettyhalliJalahalli West, Bangalore -560015.	VBhu B/.	12 Mar 2021

AUDIT COMPLIANCE

A Clinical study titled: "A double blind, placebo controlled, three arm, randomized clinical trial to evaluate the immuno boosting activity and to assess the efficacy and safety of the test products DailyTab™Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) Mfd. By LIFECARE NEURO PRODUCTS LTD, Himachal Pradesh (India) along with Standard of Care in novel corona virus (COVID-19) patients.".

This study was verified and reviewed independently according with the final protocol, the applicable Harmonized Tripartite Guidelines for Good Clinical Practice (GCP), the relevant sections of Good Laboratory Practice (GLP), local laws and regulations and the provisions of Declaration of Helsinki.

Name	Designation & Address	Signature	Date (DD MMM YYYY)
Dr. Vandana Bhat BDS	Executive- Quality Assurance Pharexcel Consulting 11, 10th Cross, AYR lay out, Shettyhalli, Jalahalli West, Bangalore -560015.	Vandana Bhat PHAREXCEL CONSULTING Bangalore	12 Mar 2021

5. Report summary

Title of the Study	A double blind, placebo controlled, three arm, randomized clinical trial to evaluate the immuno boosting activity and to assess the efficacy and safety of the test products DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) Mfd. By LIFECARE NEURO PRODUCTS LTD, Himachal Pradesh (India) along with Standard of Care in novel corona virus (COVID-19) patients.
Name of Investigational product	DailyTab™ Gold (Immuno Booster) DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)
Name of Sponsor	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Name of CRO	Pharexcel Consulting 11, 10th Cross, AYR lay out, Shettyhalli Jalahalli West, Bangalore -560015.
Investigator	Dr. Giriraja K.V, MBBS, MD Consultant- General Medicine Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India

Co-investigator	Dr. G. Suman Raj, BDS Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India
Study objectives	**PRIMARY OBJECTIVE:** • To assess the immuno boosting activity of the DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) along with standard treatment as per hospital protocol on novel corona virus (COVID-19) subjects. • To assess the clinical efficacy of the DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold Immuno Booster (For cardiac, diabetic and neuro conditions) along with standard treatment as per hospital protocol on novel coronavirus (COVID-19) subjects. **SECONDARY OBEJCTIVE:** • To assess the clinical safety of the DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) along with standard treatment as per hospital protocol on novel coronavirus (COVID-19) subjects.
Study Design	**Type:** Interventional **Endpoint** : Efficacy /safety **Primary Purpose**: efficacy **Study:** Double blind **Control:** Placebo
Number of	45

subjects	
Patient disposition	45 eligible patients were randomly assigned to the three treatment groups in 1:1 ratio (15 subjects in each group).
Follow up period	7 days, 14 days and after 28 days of treatment. A telephonic follow up visit at Day 35.
Study Inclusion Criteria	Subjects were included based on following inclusion critieria. 1. Gender: Either male or female of age range 18-65 years. 2. Patients with RT-PCR confirmed diagnosis of COVID-19. 3. Patients with mild to moderate COVID-19 infection 4. Subjects willing to give written informed consent and come for a regular follow up. 5. Subjects able to take the drug orally and comply with the study protocol 6. Women of child bearing potential must have a negative urine pregnancy test prior to study entry
Study Exclusion Criteria	Subjects were excluded based on the following exclusion criteria. 1. Patients presenting severe multisystemic symptoms compatible with advanced Covid-19 and intercurrent acute or severe chronic diseases (i.e. active cancer) Presence of acute hypoxic respiratory failure 2. Requires Intensive care unit (ICU) for management of ongoing clinical status 3. Severe infection, defined as need for invasive or non-invasive ventilator support 4. Inability to intake or tolerate oral medication
Study Product, Dose	**<u>Study treatments:</u>** **Test product:** Name of product: DailyTab™ Gold (Immuno Booster)

Pharmaceutical form & Strength	Tablet
Manufacturer	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Manufacture date	08/2020
Expiry date	01/2022
Batch number	LC0H143

Test product:

Name of product	DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)
Pharmaceutical form & Strength	Tablet
Manufacturer	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Manufacture date	08/2020
Expiry date	01/2022
Batch number	LC0H145

Placebo:

Name of product	Placebo

<table>
<tr><td></td><td><table>
<tr><td>Pharmaceutical form & Strength</td><td>Tablet</td></tr>
<tr><td>Manufacturer</td><td>LIFECARE NEURO PRODUCTS LTD.
70/1 Dharampur, Sai Road,
Near Export Promotion Zone
Phase-II, Baddi - 173205,
(Distt. Solan)
Himachal Pradesh (India)</td></tr>
<tr><td>Manufacture date</td><td>08/2020</td></tr>
<tr><td>Expiry date</td><td>01/2022</td></tr>
<tr><td>Batch number</td><td>LC0L031</td></tr>
</table></td></tr>
<tr><td>Intervention / Comparator Agent dosage and administration</td><td><table>
<tr><td><u>Treatment Arm</u></td><td>Dosage and administration</td></tr>
<tr><td>DailyTab™ Gold (Immuno Booster) along with standard treatment</td><td>Dose: One tablet daily after break fast or lunch for 28 days
Dose Form: Tablet
Administration: Oral
Time of Administartion: Morning or Afternoon
Duration of treatment: 28 days</td></tr>
<tr><td>DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) along with standard treatment</td><td>Dose: One tablet daily after break fast or lunch for 28 days
Dose Form: Tablet
Administration: Oral
Time of Administartion: Morning or Afternoon
Duration of treatment: 28 days</td></tr>
<tr><td>Placebo along with standard treatment protocol</td><td>Dose: One tablet daily after break fast or lunch for 28 days
Dose Form: Tablet
Administration: Oral
Time of Administartion: Morning or Afternoon
Duration of treatment: 28 days</td></tr>
</table></td></tr>
<tr><td>Evaluations by visit</td><td>Visit 1 (Screening and Randomization visit; Day -2 to Day 1)
1. Reviewed the study with the subject (subject’s legal representative) and obtained written informed consent.
2. Assigned the subject with a unique screening number.
3. Recorded demographics data.
4. Recorded medical and medication history</td></tr>
</table>

	5. Performed a complete physical examination 6. Reviewed the RT-PCR and chest x-ray results 7. Assessed the Inclusion and exclusion criteria 8. Collected blood for clinical laboratory tests (Hematology, Biochemistry and Urine analysis). 9. Assigned subjects a unique study ID/number 10. Randomized subjects and assigned them groups 11. Initiated subject diary 12. Performed and recorded vital signs 13. Baseline physician clinical symptoms assessed 14. Dispensed study drug 15. Informed the subject on the next visit due date **Visit 2 (Follow up visit; Day 7)** 1. Recorded any Adverse Experiences / Event. Recorded concomitant medications. Performed a complete physical examination. Performed and recorded vital signs. 2. Reviewed the subject diary 3. Physician clinical symptoms assessed 4. Reviewed the subject's clinical symptoms assessment from Day 1 to Day 7 Additional subject questionnaire assessment 5. Dispensed study drug 6. Informed the subject on the next visit due date **Visit 3 (Follow up visit; Day 14)** 1. Recorded any Adverse Experiences / Event. Reviewed the subject diary. 2. Recorded prior and concomitant medications. Performed a complete physical examination. Performed and recorded vital signs. 3. Physician clinical symptoms assessed 4. Reviewed the subject's clinical symptoms assessment from Day 8 to Day 14 Performed the Additional subject questionnaire assessment 5. Dispensed study drug

	6. Informed the subject on the next visit due date. **Visit 4 (Follow-up visit/End of visit- Day 28)** 1. Recorded all Adverse Experiences 2. Reviewed the subject diary 3. Recorded prior and concomitant medications. 4. Performed a complete physical examination. 5. Performed and recorded vital signs. 6. Physician clinical symptoms assessed 7. Reviewed the subject's clinical symptoms assessment from Day 15 to Day 28 8. Additional subject questionnaire assessed 9. Performed/Reviewed the RT-PCR/Chest X-ray results 10. Collected blood for clinical laboratory tests (Hematology, Biochemistry and Urine analysis). 11. Performed the additional subject procedures **Early Withdrawal Visit** 1. Recorded all Adverse Experiences and/or Review subject diary for adverse experiences and exclusionary medication use. 2. Recorded changes to concomitant medications. 3. Performed complete physical examination. 4. Performed and recorded vital signs. 5. Performed/reviewed RT-PCR and chest x-ray test results 6. Physician clinical symptoms assessed 7. Reviewed the subject's clinical symptoms assessment 8. Collected blood for clinical laboratory tests: Bio-Chemistry and Hematology **Follow up Telephonic visit (Day 35)** 1. A telephonic follow up was done on day 35. 2. Recorded any Adverse Experiences 3. Subject's global assessment of symptoms and enquiry about overall health.

	4. Subjects are encouraged to reach out in case of any discomfort.
Primary Outcome	• Clinical cure based on Clinicians assessment of symptoms Time points – (Day 1, Day 7, Day 14, Day 28)
Secondary Outcome	• Changes in RTPCR test results(Day 1,Day 14/Day28) • Clinical status as assessed by the 7-point ordinal Covid-19 scale (Day1, Day7, Day14 and Day28). • Change in clinical laboratory findings • Subject global assessment of symptoms • Improvement in Oxygen saturation levels • Changes in chest finding using x-ray • Necessity of invasive assisted ventilation • Necessity of non-invasive assisted ventilation • Intensive care unit admission • Post-anesthesia care unit admission • Hospital admission • Medical consultation • Homecare and isolation time • Bed rest time • Subject perception of recovery
Statistical Analysis	All the data was analysed using SAS 9.1 version. All data was expressed as mean ± SD or Percentage. A probability $p < 0.05$ is considered significant.
Ethical Conduct of the study	The study was initiated after written approval from Institutional Ethics Committee and also after registration of this trial in CTRI. The trial was conducted as per the ICMR Guidelines for Biomedical Research on Human subjects, ICH E6 R2 Guidelines, Schedule Y (2017), Declaration of Helsinki (Brazil, 2013) and in accordance with other applicable guidelines.

Efficacy and Safety Results	Out of 54 subjects screened, 45 subjects were enrolled and 9 were screen failures. 5 subjects of screen failures were severe covid-19 subjects, 2 subjects were ICF withdrawn and 2 subjects were need of ICU. 45 patients who underwent randomization, 15 patients were assigned to receive DailyTab™ Gold (Immuno Booster) + Standard treatment, 15 patients were assigned to receive Placebo+ Standard treatment and 15 patients were assigned to receive DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)+ Standard treatment. The mean age of the subjects were 37, 38.14 and 39.47 years in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) group, respectively + Standard treatment. 28 subjects were male subjects and 17 subjects were females in the complete study. In DailyTab™ Gold (Immuno Booster) + Standard treatment group, 11 were males and 4 were females. In placebo treatment group, 5 were males and 10 were females. In DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, 12 were males and 3 were females. The mean BMI of the subjects were 27.08, 27.54 and 27.29 kg/m^2 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)+ Standard treatment group, respectively. In DailyTab™ Gold (Immuno Booster) + Standard treatment group, pre-existing medical conditions were hysterectomy, diabetes mellitus and hypertension. In Placebo + Standard treatment group, pre-existing medical conditions were hypothyroidism, diabetes mellitus and hypertension. In DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) + Standard treatment, pre-existing

	medical conditions were hypothyroidism, and hypertension. There were no significant difference in baseline data between the groups. There were no difference in standard treatments given between the groups. One tablet daily was consumed after break fast or lunch for 28 days. All subjects were treatment compliant along with their standard treatment. In DailyTab™ Gold (Immuno Booster) + Standard treatment group, 13 of 15 subjects were found with no clinical or virological evidence of infection after treatment for 28 days. In Placebo + Standard treatment group, 3 of 15 subjects were found with no clinical or virological evidence of infection after treatment for 28 days. In DailyTab™Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, 14 of 15 subjects were found with no clinical or virological evidence of infection after treatment for 28 days. The P-values were found statistical significant when compared to placebo in both treatment groups. On day 14 post treatment, in DailyTab™ Gold (Immuno Booster) + Standard treatment group, 14 out of 15 subjects (93.33%) were virologically cured, in placebo +Standard treatment group 8 of 15 subjects (53.33%) were virologically cured and in DailyTab™Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, 100% subjects were virologically cured. The differences were statistical significant between the groups ($p<0.05$). Symptom disappearance percentage was were high in DailyTab™Gold (Immuno Booster) + Standard treatment group and DailyTab™Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to the Placebo+standard treatment group. The mean scores of symptoms in scale of Nil-0, Mild- 1, Moderate-2 and Severe- 3 were assessed from Day 1 to Day 28 by subject

	questionnaire and showed improvement in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared with day 1 scores and also when compared to the Placebo +Standard treatment. 13 out of 15 subjects (86.67%) had improved chest x-ray results in DailyTab™ Gold (Immuno Booster) + Standard treatment group and 14 out of 15 subjects (93.33%) had improved chest x-ray results in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group. 7 out of 15 (46.67) subjects improved in Placebo plus standard treatment group. The mean results of Hs-CRP values (mg/L) at baseline were 103.95, 88.04 and 78.06 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group. After 28 days of treatment the Hs-CRP changed values were 3.35, 75.14 and 15.61, respectively. The % change of Hs-CRP values were -96.77, -14.65 and -80 when compared to the baseline. At baseline, the mean values of IL-6 values were 20.6, 19.17 and 20.49 pg/mL in DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment, respectively. After treatment for 28 days, the values were 4.87, 22.13 and 4.21 pg/mL, respectively. The % change of IL-6 was -76.36, 15.44 and -79.45 in DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment, respectively. The results were significant between the groups at $P<0.05$. The mean results of Blood Oxygen saturation (SpO_2) values were 90, 93.4, 95.93 and 97.8 % at baseline, Day 7, Day 14 and Day 28 in

	DailyTab™ Gold (Immuno Booster) + Standard treatment group, respectively. The mean results of Blood Oxygen saturation (SpO_2) values were 90.7, 92.79, 93.93 % and 94.5 at baseline, Day 7, Day 14 and Day 28 in Placebo+ Standard treatment group, respectively. The mean results of Blood Oxygen saturation (SpO_2) values were 90.71, 94.13, 96.47 and 97.20 % at baseline, Day 7, Day 14 and Day 28 in DailyTab™ (Gold Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group, respectively. The number of subjects who had normal ECG values were 7, 6 and 6 at baseline.These were improved to 12, 8 and 11 out of 15 subjects in DailyTab™ Gold (Immuno Booster) +Standard treatment group, Placebo +Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group. The % improvement of normal ECG from baseline were 71.43%, 33.33% and 83.33% in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group, respectively. Medical consultation, Home care and isolation time and Bed rest time were improved in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group when compared to the placebo +Standard treatment group. There were no adverse events reported. No serious adverse events and deaths were reported. There were no significant change in hematological, biochemical and urine anlaysis values between DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+ Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment, respectively.

	Urine pregnancy test was negative for the female patients of child bearing potential. All female subjects tests had shown negative urine pregnancy tests in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group. All the vital signs were found with in the normal range at day 28. The subjects maintained health at post- follow up visit at Day 35 in DailyTab Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group. There were no worsening of clinical symptoms after treatment in three groups. There were no protocol violations and deviations reported. There were no patients lost to follow up.
Conclusion	In conclusion, overall clinical and virological cure improved with DailyTab™ Gold (Immuno Booster) along with Standard treatment and also DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with Standard treatment. Both products were very effective in controlling clinical and virological cure in covid 19 when compared to the placebo+standard treatment. The change rate of Hs-C reactive protein and IL-6 were favourable to DailyTab™Gold (Immuno Booster) along with Standard treatment group and DailyTab™Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with Standard treatment group when compared to placebo and standard treatment group. Both the test groups along with standard treatment showed improvement in blood oxygen saturation (SpO2) levels, normal Chest X ray and ECG when compared with Placebo + Standard treatment group. No adverse events or serious adverse events were reported. All the hematological, biochemical and Urine analysis tests were found

	normal at baseline and post study. Overall DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) were very effective in the management of the Covid-19 disease. The DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) were tolerated very well.
Date of Report	12 March 2021

6. Table of Contents

CONTENTS

7. List of Tables

8. List of Figures

9. List of Abbreviations

ADE	Adverse Drug Event
ARDS	Acute Respiratory Distress Syndrome
ALT	Alanine Amino transferase
AST	Aspartate Amino transferase
BUN	Blood Urea Nitrogen
CFR	Code of Federal Regulations
CRF	Case Report Form
CRP	C-reactive Protein
DMC	Data Monitoring Committee
DSMB	Data Safety Monitoring Board
ESR	Erythrocyte Sedimentation Rate
FDA	Food and Drug Administration
GCP	Good Clinical Practice
GGT	Gamma-glutamyl Transferase
ICF	Informed Consent Form
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IEC	Independent Ethics Committee
IRB	Institutional Review Board
IV	Intravenous
LDH	Lactate dehydrogenase
mEq	Milliequivalent
PI	Principal Investigator
PK	Pharmacokinetic
MERS-CoV	Middle East respiratory syndrome coronavirus
SAE	Serious Adverse Experience/Event
SARS-CoV-1	Severe acute respiratory syndrome coronavirus 1
SARS- CoV-2	Severe acute respiratory syndrome coronavirus 2
SGOT	Serum Glutamic Oxaloacetic Transaminase
SGPT	Serum Glutamate Pyruvate Transaminase
RBS	Random blood sugar
SOC	Standard of care

10. Ethics

Written informed consent was obtained from the subject(s) before the start of the trial and after the approval from IEC. Ethics Committee notifications as per the GCP guidelines issued by Central Drugs Standard Control Organization and ethical guidelines for biomedical research on human subjects issued by Indian Council of Medical Research were followed during the conduct of the study.

Institutional Ethics Committee (IEC)

The study protocol was reviewed by the Institutional Ethics Committee (IEC), Rajalakshmi Hospital & Research center,Lakshmipura Main Road,Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India

Site Name	Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India
Investigator	Dr.Giriraja KV Consultant- General Medicine
Ethics Committee	Institutional Ethics Committee, RAJALAKSHMI HOSPITAL, BENGALURU
Date of approval of the final protocol	26 Dec 2020

Ethical Conduct of the study

The study was performed in accordance with the current version of the declaration of Helsinki (Brazil, 2013) and in compliance to the current ICMR Guidelines for Biomedical Research on Human Patients, Schedule Y (amended version 2015) of Drug and Cosmetics Act, ICH GCP Guidelines and other applicable regulatory guidelines.

Patient Information and Consent

All patients provided written informed consent to participate in the study prior to being screened. The patient information sheet detailed the procedures involved in the study (aims, methodology, potential risks and anticipated benefits) and the investigator explained

these to each patient. The patient signed the consent form to indicate that the information had been explained and understood. The patients were allowed to take ample time to consider the information presented before signing and dating the informed consent form to indicate that they fully understood the information, and willingly volunteered to participate in the study. The patients were given a copy of the signed informed consent form for their information. The original informed consent documents were kept in a confidential file in the Investigators site record.

11. Investigators and study administrative structure

SPONSOR	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
CRO	Pharexcel Consulting 11, 10th Cross, AYR lay out, Shettyhalli Jalahalli West, Bangalore -560015.
PRINCIPAL INVESTIGATOR	Dr.Giriraja K V MBBS, MD Consultant- General Medicicne Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura, Banglore-560097. Bangalore, Karnataka, India
CO-INVESTIGATOR	Dr. G. Suman Raj BDS Rajalakshmi Hospital & Research Center Lakshmipura Main Road, Vidyaranyapura, Banglore-560097. Bangalore, Karnataka, India

ETHICS COMMITTEE	Institutional ethics Committee, Rajalakshmi hospital& Research Center Lakshmipura Main Road, Vidyaranyapura, Banglore-560097. Bangalore, Karnataka, India.
STUDY SITE	Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India
NAME AND ADDRESS OF LABORATORY	Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India
REPORT GENERATION	Mounika Jutur M.Pharm Clinical Research Associate
MEDICAL MONITOR/ AUDITOR	Dr. Vandana Bhat BDS Medical monitor
BIOSTATISTICIAN	Mounika Jutur M.Pharm Clinical Research Associate

12. Introduction

The COVID-19 is an acute and contagious disease characterized by pneumonia and ARDS. The disease is caused by SARS-CoV-2, which belongs to the family of *Coronaviridae* along with MERS-CoV and SARS-CoV-1. The virus has the positive-sense RNA as its genome encoding for ~26 proteins that work together for the virus survival, replication, and spread in the host. The virus gets transmitted through the contact of aerosol droplets from infected persons. The pathogenesis of COVID-19 is highly complex and involves suppression of host antiviral and innate immune response, induction of oxidative stress followed by hyper inflammation described as the "cytokine storm," causing the acute lung injury, tissue fibrosis, and pneumonia. Currently, several vaccines and drugs are being evaluated for their efficacy, safety, and for determination of doses for COVID-19 and this requires considerable time for their validation. Therefore, exploring the repurposing of natural compounds may provide alternatives against COVID-19. Several nutraceuticals have a proven ability of immune-boosting, antiviral, antioxidant, anti-inflammatory effects. These include Zn, vitamin D, vitamin C, curcumin, cinnamaldehyde, probiotics, selenium, lactoferrin, quercetin, etc. Grouping some of these phytonutrients in the right combination in the form of a food supplement may help to boost the immune system, prevent virus spread, preclude the disease progression to severe stage, and further suppress the hyper inflammation providing both prophylactic and therapeutic support against COVID-19.

Strategies to counteract the SARS-CoV-2 infection using food supplements:

From the point of prevention, phase 1 is crucial as individuals in this stage are carriers, they can spread the infection unknowingly. Management of individuals in phase 1, along with mounting specific adaptive immune response, and use of antivirals is critical to prevent the virus entry, replication as well as the disease progression to phase 2. Therefore, global strategies may include administration of external antiviral, and or immune-boosting food supplements. During the phase 2 of the infection, in addition to maintaining the general health condition of affected patients, the line of treatment may be focused on adapting the strategies including the use of nutritional supplements that can suppress the ongoing oxidative stress, acute-inflammation and cytokine storm so that destruction and

damage caused to affected tissues is prevented. In summary, in addition to symptomatic treatment, strategies to counteract the SARS-CoV-2 infection is to boost the immune response in phase 1 while suppressing it in the second phase could be effective. Several shreds of evidence indicate that many nutritional supplements from various spices, herbs, fruits, roots, and vegetables can reduce the risk or severity of a wide range of viral infections by boosting the immune response, particularly among people with inadequate dietary sources and also by their anti-inflammatory, free radical scavenging, and viricidal functions. These nutrients can be repurposed in mitigating the pathological effects induced by the SARS-CoV-2 infection. Therefore, the use of natural compounds may provide an alternative prophylactic and therapeutic support along with the therapy for COVID-19.

DailyTab™ Gold (Immuno Booster):

DailyTab™ Gold (Immuno Booster) is a special doctor formulated supplement that boosts immunity with a formulation of 27 premium active constituents like Natural Astaxanthin, Apple Cider Vinegar, Vitamin C, Zinc, Curcumin (Haldi), Clove Extract (Laung), Cinnamon Extract (Dalchini), Liquorice Extract (Mulethi), Boswellia serrata and Cranberry extract (Lycopene (10%), Biotin, Thiamine Mononitrate, Cyanocobalamin, Riboflavin,etc as below table) etc.

Pack of 28 tablets in a calender pack.

Table1: List of the herbal components

S. No	Name of ingredient	Qty
1.	Natural Astaxanthin	2 mg
2.	Vitamin C	40 mg
3.	Elemental Zinc	12 mg
4.	Taurine	100 mg
5.	*Boswellia serrata* Extract	25 mg
6.	*Pyrus malus* Extract (Apple Cider Vinegar)	50 mg

7.	Cinnamon Extract (30%)	30 mg
8.	Liquorice Extract (20%)	30 mg
9.	Clove Extract (3%)	30 mg
10.	Curcumin (*Curcuma longa*)	50 mg
11.	Green Tea Extract	25 mg
12.	Cranberry Extract (10%)	25 mg
13.	Lycopene (10%)	2500 mcg
14.	Biotin	30 mg
15.	Thiamine Mononitrate	1.7 mg
16.	Vitamin-E Acetate (50%)	10 mg
17.	Vitamin A	0.6 mg
18.	Cyanocobalamin	1.0 mcg
19.	Sodium Selenite eq. to Elemental Selenium	40 mcg
20.	Riboflavin	2.1 mg
21.	Pyridoxine Hydrochloride	2 mg
22.	Nicotinamide	21 mg
23.	Folic Acid	200 mcg
24.	Elemental Boron	150 mcg
25.	Elemental Chromium	50 mcg

26.	Elemental Magnesium	10 mg
27.	Elemental Manganese	2.5 mg

A powerful blend of scientifically backed ingredients like Natural Astaxanthin, Curcumin, Boswellia serrata etc. Natural Astaxanthin is:

(a) 6000 times more powerful than Vitamin C.

(b) 794 Times stronger than CoQ10.

(c) 550 Times stronger than Vitamin E.

(d) 36 Times stronger than Beta-Carotene.

Dosage: Consume one tablet daily after breakfast or lunch.

DailyTab™ Gold (Immuno Booster For Cardiac, Diabetic and Neuro conditions):

DailyTab™ Gold (Immuno Booster For Cardiac, Diabetic and Neuro conditions) is a special doctor formulated supplement that boosts immunity with a formulation of 29 premium active constituents like Natural Astaxanthin, Apple Cider Vinegar, Vitamin C, Zinc, Cranberry extract, Alpha LipoicAcid, Resveratrol, Cinnamon Extract (Dalchini), Clove Extract (Laung) etc. It is available in a convenient 28 Tablets Calendar Pack" for one month course.

Dosage: Consume one tablet daily after breakfast or lunch.

Composition:

List of the herbal components

	Name of ingredient	**Qty**
1.	Natural Astaxanthin	2 mg
2.	Resveratrol	25 mg
3.	Alpha Lipoic Acid	50 mg
4.	Vitamin C	40 mg
5.	Elemental Zinc	12 mg

6.	Taurine	100 mg
7.	*Boswellia serrata* Extract	25 mg
8.	*Pyrus malus* Extract (Apple Cider Vinegar)	50 mg
9.	Cinnamon Extract (30%)	30 mg
10.	Liquorice Extract (20%)	30 mg
11.	Clove Extract (3%)	30 mg
12.	Curcumin (*Curcuma longa*)	50 mg
13.	Green Tea Extract	25 mg
14.	Cranberry Extract (10%)	25 mg
15.	Lycopene (10%)	2500 mcg
16.	Biotin	30 mg
17.	Thiamine Mononitrate	1.7 mg
18.	Vitamin E Acetate (50%)	10 mg
19.	Vitamin A	0.6 mg
20.	Cyanocobalamin	1.0 mcg
21.	Sodium Selenite eq. to Elemental Selenium	40 mcg
22.	Riboflavin	2.1 mg
23.	Pyridoxine Hydrochloride	2 mg

24.	Nicotinamide	21 mg
25.	Folic Acid	200 mcg
26.	Elemental Boron	150 mcg
27.	Elemental Chromium	50 mcg
28.	Elemental Magnesium	10 mg
29.	Elemental Manganese	2.5 mg

A powerful blend of scientifically backed ingredients like Natural Astaxanthin, Resveratrol, Curcumin.
Natural Astaxanthin is:

(a) 6000 times more powerful than Vitamin C.

(b) 794 Times stronger than Co-Q10.

(c) 550 Times stronger than Vitamin E.

(d) 36 Times stronger than Beta-Carotene.

Natural Astaxanthln: Astaxanthin is the most potent singlet oxygen quencher. It prevents damage to body cells. It is one of the most powerful naturally occurring antioxidants known for supporting body immunity and healthy eyes. Natural Astaxanthin's intracellular antioxidant activity is approximately 90 times stronger than Synthetic Astaxanthin's (Flagnier et al., 2015). Natural Astaxanthin is a more effective antioxidant than other carotenoids due to its higher electron transfer activity (1-lan et al., 2009).Natural Astaxanthin is more stable than zeaxanthin, centhaxanthin and beta-carotene during lipid peroxidation (Jorgensen and Skibsted, 1993).

Resveratrol: It is an antioxidant with potential Cardio protective, Neuroprotective, Anti-inflammatory and Anticancer properties.

Alpha Lipoic Acid (ALA): It is widely used in conditions such as Diabetes and Obesity. It also supports energy production at cellular level.

Vitamin C: An essential vitamin and antioxidant that stimulates the immune system and helps build healthy collagen, skin, cartilage and bones.

Elemental Zinc: An essential mineral that is required for normal immunity response, protein synthesis and also supports sexual health.

Taurine: An amino acid that supports several metabolic processes and supports anti oxidation. It also supports Heart and Liver functions.

Cranberry extract: Consists of proanthocyanidins that are believed to help boost immunity and prevent UTIs.

Apple Cider Vinegar: Known for its antimicrobial, immunity supporting and antioxidant effects.

Curcumin or *Curcuma longa*: A natural anti-inflammatory agent that matches the effectiveness of powerful anti-inflammatory drugs, without the side effects.

***Boswellia serrata* Extract:** A powerful anti-inflammatory extract that protects the gut & skin. It improves joint function and may also support cognition and mental health.

Cinnamon: which was earlier regarded as a 'Gift fit for kings' is a powerful antioxidant that supports in reducing blood sugar.

Licorice herb extract: It has proven potent immunomodulatory and antiviral activities. The extracts of licorice have a positive effect on the immune system. It can be used to optimize Immune response and improve the productive performance. It is also potentially beneficial for treating skin conditions, indigestion problems, respiratory conditions and cavities.

Clove extract: Anti-infammatory and antibacterial substance that contains high amounts of eugenol, a compound with both anti-inflammatory and anti-viral properties. It also contains Kaempferol and Rhamnetin, flavonoids that share the same properties as Eugenol. It also supports the functioning of the immune system. Cloves also contain high amounts of antioxidants.

Lycopene: One of the best antioxidants that has been found to be effective in viral infections. Cardio-vascular diseases and metabolic syndromes.

Green Tea Extract: Contains polyphenols that are powerful antioxidants and free radical scavengers. Many studies have shown it to promote weight loss and support healthy arteries.

Biotin: Supports healthy skin, nails and hair.

Thiamine Mononitrate: Essential for normal body growth and helps to maintain proper functioning of the heart, nervous and digestive systems.

STUDY RATIONALE

Both DailyTab™ Gold (Immuno Booster) and Daily Tab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) is a special doctor formulated supplement that boosts immunity with a formulation of 27 and 29 premium active constituents like Natural Astaxanthin, Apple Cider Vinegar, Vitamin C, Zinc, Cranberry extract, Alpha Lipoic Acid, Resveratrol, Cinnamon Extract (Dalchini), Clove Extract (Laung) etc. The JinYintan Hospital in Wuhan, China, where the first 41 known patients were treated, has already launched a randomized, controlled trial of the anti-HIV drug combination of lopinavir and ritonavir, according to a 24 January report by a group of Chinese scientists in The Lancet. The combination targets protease, an enzyme used by both HIV and corona virus to cut up proteins when they make new copies of themselves. A study published in 2004 showed that the combination showed "substantial clinical benefit" when given to patients who had severe acute respiratory syndrome (SARS), which is caused by a corona virus similar to novel coronavirus-2019.

Given the circumstances with the Covid-19, where the treatments are still underway, an agent like DailyTab™ Gold (Immuno booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) which has antiviral as well as immune-modulator activity definitely stands a chance. DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) is a doctor formulated supplements compound and can produce synergistic anti-viral effect, which might provide some aid in the treatment and prevention of novel coronavirus (Covid-19) as well as improve the overall condition of existing patients with its immuno-stimulant activity.

Risk / Benefit Assessment

Known ingredients of DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) have not revealed any potent risk as evidenced by literature in clinical study. Also owing to its immune-modulator and antiviral activities it might boost the immunity of the patients and help ease the symptoms.

13. Study Objectives

Primary Objective:

To assess the immuno boosting activity of the DailyTab™ Gold (Immuno Booster) and Daily Tab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) along with standard treatment as per hospital protocol on novel corona virus (COVID-19) positive subjects.

To assess the clinical efficacy of the DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) along with standard treatment as per hospital protocol on novel coronavirus (COVID-19) positive subjects.

Secondary Objectives:

To assess the clinical safety of the DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) along with standard treatment as per hospital protocol on novel coronavirus (COVID-19) positive subjects.

14. Investigational Plan

Over all Study Design and Plan: Description

This was a double blind, placebo controlled, three arm clinical trial. 45 number of subjects were planned. Group-1, n=15 of the subjects were assigned to DailyTab™ Gold (Immuno Booster) with SOC and Group-2, n=15 were assigned to the DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) with SOC and Group-3, n=15 were assigned to the Placebo with SOC.

Evaluations were taken at baseline with follow up period for 7 days, 14 days and after 28 days of treatment. Screening data was reviewed to determine subject eligibility. Subjects who met all inclusion criteria and none of the exclusion criteria were entered into the study.

Treatments studied:

a. DailyTab™ Gold (Immuno Booster) + Standard treatment
b. DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions) + Standard treatment
c. Placebo + Standard treatment

The standard treatment for Covid-19 was as per the hospital protocol.

Total duration of the study was expected to be 5 weeks per each subject, 4 weeks treatment period and 1 week follow up period. The screening duration was -2 to day 0.

Patient population and number of subjects included:

Subjects with a confirmed diagnosis of Covid-19 who meet the inclusion criteria and none of the exclusion criteria were eligible for participation in this study. That included mostly mild to moderate COVID-19 patients.

Number of Subjects: 45

Level and method of blinding

This was a double-blind study.

Kind of control and study configuration

Placebo was used as a control.

Method of assigned to the treatment (Randomization)

45 eligible patients in three groups randomly assigned either to study treatments or placebo in 1:1:1 ratio using a SAS based computer generated randomization scheme developed by the study data management provider.

Plan of the Study

There were three groups in the study comprising 15 subjects each

a. DailyTab™ Gold (Immuno Booster) + Standard treatment
b. DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) + Standard treatment

c. Placebo+ Standard treatment

Schedule of Study Visits

Table 1: Schedule of study visits

	VISIT 1 (Day 0-Screening and randomization visit)[a]	**VISIT 2 (Day 7- follow up**	**VISIT 3 (Day 14-follow up)[a]**	**VISIT 4 (Day 28 follow up and end of visit)[a]**	**VISIT 5 (Day 35- Telephonic follow up)**
Informed Consent	**X**				
Demography	**X**				
Medical History	**X**				
Complete Physical Exam	**X**				
Abbreviated Physical Exam	**X**	**X**	**X**	**X**	
Height	**X**				
Weight	**X**				
Vital Signs	**X**	**X**	**X**	**X**	
Urine Pregnancy Test	**X**			**X**	
CBC counts	**X**			**X**	
RT-PCR Test	**X**		**X**	**X***	
Biochemistry	**X**			**X**	
C-Reactive Protein	**X**			**X**	
Urine analysis	**X**			**X**	
Marker IL-6	**X**			**X**	
Randomization	**X**				
Dispensing or Administration of Study Drug	**X**	**X**	**X**		
Physician and subject global symptom assessment	**X**	**X**	**X**	**X**	
Counting of Returned Study product				**X**	
Initiate Subject Diary	**X**				
Subject Diary Review		**X**	**X**	**X**	
Prior and Concomitant Medication Review	**X**	**X**	**X**	**X**	
Adverse Events	**X**	**X**	**X**	**X**	**X**

*If Day 14 positive, the test will be repeated in Day 28.
[a]±2 days

15. Study Procedure

Prior to conducting any study-related activities, written informed consent were received, which were signed and dated by the subject.

Baseline/Screening

Dose, route, unit frequency of administration, and indication for administration and dates of medication were captured on study Days 1to 28 and at early termination when applicable.

Demographics

Demographic information (date of birth, gender, race) will be recorded at Screening.

Medical History

Relevant medical history, including history of current disease, other pertinent respiratory history, and information regarding underlying diseases will be recorded at Screening.

Physical Examination

A complete physical examination was performed by either the investigator or a sub-investigatorwho was a physician at Visit 1.Qualified staff (MD, NP, RN and PA) were completed the abbreviated physical examination all other visits. Abnormal physical examination findings were followed by a physician or other qualified staff at the next scheduled visit.

Vital Signs

Body temperature, blood pressure, pulse and respiration rate were measured after resting for 5 minutes on study Day 1, Day 7, Day 14 and Day 28.

Adverse Events

Information regarding occurrence of adverse events was captured through out the study. Duration (starts and stop dates), severity/grade, outcome, treatment and relation to study drug was recorded on the case report form (CRF).

Clinical Laboratory Measurements

Hematology
Blood was obtained and sent to clinical hematology lab/central lab for a complete blood count for assessment of systemic evidence for infection and/or inflammation on Day 0 and Day 28.

Blood Chemistry Profile
Blood was obtained and sent to clinical chemistry/central lab for determination of Total bilirubin, Alkaline phosphatase, ALT, AST, Total protein, Albumin, Creatinine, Sodium, Potassium, BUN, IL-6 and CRP on Day 0 and Day 28.

Urine analysis:
Complete urine analysis was done on Day 0 and Day 28.

Pregnancy Test
A urine pregnancy test was done from female subjects who were of child bearing age prior to their participation in the study.

16. Visit schedule:

Visit 1 (Screening and Randomization visit; Day -2 to Day 1)

1. Review the study with the subject (subject's legal representative) and obtain written informed consent.
2. Assign the subject with a unique screening number.
3. Record demographics data.
4. Record medical and medication history
5. Perform a complete physical examination
6. Review the RT-PCR and chest x-ray results
7. Assess the Inclusion and exclusion criteria
8. Collect blood for clinical laboratory tests (Hematology, Biochemistry and Urine analysis).
9. Assign subjects a unique study ID/number
10. Randomize subjects and assign them groups
11. Initiate subject diary

12. Perform and record vital signs
13. Baseline physician clinical symptoms assessment
14. Dispense study drug
15. Inform the subject on the next visit due date

Visit 2 (Follow up visit; Day 7)

1. Record any Adverse Experiences / Event
2. Record concomitant medications.
3. Perform a complete physical examination.
4. Perform and record vital signs.
5. Review the subject diary
6. Physician clinical symptoms assessment
7. Review the subject's clinical symptoms assessment from Day 1 to Day 7
8. Additional subject questionnaire assessment
9. Dispense study drug
10. Inform the subject on the next visit due date

Visit 3 (Follow up visit; Day 14)

1. Record any Adverse Experiences / Event
2. Review the subject diary
3. Record prior and concomitant medications.
4. Perform a complete physical examination.
5. Perform and record vital signs.
6. Physician clinical symptoms assessment
7. Review the subject's clinical symptoms assessment from Day 8 to Day 14
8. Perform the Additional subject questionnaire assessment
9. Dispense study drug
10. Inform the subject on the next visit due date

Visit 4 (Follow-up visit/End of visit- Day 28)

1. Record any Adverse Experiences
2. Review the subject diary
3. Record prior and concomitant medications.
4. Perform a complete physical examination.
5. Perform and record vital signs.

6. Physician clinical symptoms assessment
7. Review the subject's clinical symptoms assessment from Day 15 to Day 28
8. Additional subject questionnaire assessment
9. Perform/Review the RT-PCR/Chest X-ray results
10. Collect blood for clinical laboratory tests (Hematology, Biochemistry and Urine analysis).
11. Perform the additional subject procedures

Early Withdrawal Visit

1. Record any Adverse Experiences and/or Review subject diary for adverse experiences and exclusionary medication use.
2. Record changes to concomitant medications.
3. Perform complete physical examination.
4. Perform and record vital signs.
5. Perform/review RT-PCR and chest x-ray test results
6. Physician clinical symptoms assessment
7. Review the subject's clinical symptoms assessment
8. Collect blood for clinical laboratory tests: Bio-Chemistry and Hematology

Follow up (Day 35)

A telephonic follow up would be done at day 35.

- Record any Adverse Experiences
- Subject's global assessment of symptoms and enquire about overall health.
- Subjects should be encouraged to reach out in case of any discomfort.

17. Discussion of Study Design, Including the choice of control group

The study was designed with 45 subjects as a prospective interventional study compared with placebo as a control. The subjects were provided either study products or placebo along with standard of treatment. The clinical phase of the study was completed in 28 days.A telephonic follow up was done up to 35 days.

18. Selection of Study Population

Inclusion Criteria

Subjects were included based on following inclusion critieria

- Gender: Either male or female of age range 18-65 years.
- Patients with RT-PCR confirmed diagnosis of COVID-19.
- Patients with mild to moderate COVID-19 infection
- Subjects willing to give written informed consent and come for a regular follow-up.
- Subjects able to take the drug orally and comply with the study protocol
- Women of child bearing potential must have a negative urine pregnancy test prior to study entry.

Exclusion Criteria

Subjects were excluded based on following exclusion criteria.

- Patients presenting severe multisystemic symptoms compatible with advanced Covid-19 and intercurrent acute or severe chronic diseases (i.e. active cancer)
- Presence of acute hypoxic respiratory failure
- Requires Intensive care unit (ICU) care for management of ongoing clinical status
- Severe infection defined as need for invasive or non-invasive ventilator support
- Inability to intake or tolerate oral medication
- Category 6 or 5 based on modified 7-category ordinal scale of clinical status
- Clinical prognostic non-survival, palliative care, and have no response to supportive treatment within three hours of admission
- Pregnant or lactating subjects
- With any secondary complication such as uncontrolled diabetes, cancer, HIV or uncontrolled hypertension.

19. Treatments

Treatment Administered

There were three treatment arms. In one arm the experimental treatment DailyTab™ Gold was administered along with the standard treatment as per the hospital protocol, at the dose of 1 Tablet a day either in the morning or afternoon orally after having food,

In The Second arm the experimental treatment Daily Tab™ Gold Immuno Booster (For cardiac, Diabetics and Neuro conditions) was administered along with the standard treatment as per the hospital protocol, at the dose of 1 Tablet a day either in the morning or afternoon orally after having food

In Third treatment arm placebo along with the standard treatment as per the hospital protocol, at the dose of 1 tablet a day either in the morning or afternoong orally after having food.

Identity of Investigational products:

Test product-A

Name of product	DailyTab™ Gold (Immuno Booster)
Pharmaceutical form & Strength	Tablet
Manufacturer	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Manufacture date	08/2020
Expiry date	01/2022
Batch number	LC0H143

Placebo: Code B

Name of product	PLACEBO
Pharmaceutical form & Strength	Tablet
Manufacturer	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Manufacture date	08/2020
Expiry date	01/2022
Batch number	LC0L031

Test product- Code C

Name of product	DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)
Pharmaceutical form & Strength	Tablet
Manufacturer	LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)
Manufacture date	08/2020
Expiry date	01/2022
Batch number	LC0H145

Method of Assigning patients to Treatment Groups

45 eligible patients were randomly assigned to study products or placebo treatment groups in 1:1:1 ratio using a SAS based computer generated randomization scheme developed by the study data management provider.

The randomization scheme was generated by the CRO and approved by sponsor and the patients were centrally allocated to the treatment groups. The detailed description of the randomization method is given below. Investigator and subjects were blinded to the study products.

Table 2: Randomization schedule

S. No	Patient ID	Treatment group
1.	001	B
2.	002	A
3.	003	C
4.	004	A
5.	005	B
6.	006	C
7.	007	B
8.	008	C
9.	009	A
10.	010	C

11.	011	A
12.	012	B
13.	013	C
14.	014	B
15.	015	A
16.	016	A
17.	017	C
18.	018	B
19.	019	C
20.	020	A
21.	021	B
22.	022	C
23.	023	B
24.	024	A
25.	025	B
26.	026	C
27.	027	A
28.	028	C
29.	029	A
30.	030	B
31.	031	B
32.	032	C
33.	033	A

34.	034	C
35.	035	A
36.	036	B
37.	037	A
38.	038	C
39.	039	B
40.	040	B
41.	041	A
42.	042	C
43.	043	A
44.	044	C
45.	045	B

Study Code "A"

DailyTab™ Gold (Immuno Booster)

Batch Number: LC0H143

Mfg. date: 08/2020

Exp. Date: 18 Months from the date of Mfg

Study code 'B'

Placebo

Batch Number: LC0L031

Mfg. date: 08/2020

Exp. Date: 18 Months from the date of Mfg

Study code 'C'

DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions)

Batch Number: LC0H145

Mfg. date: 08/2020

Exp. Date: 18 Months from the date of Mfg

Selection of Doses in the Study

Dose of this formulation was chosen on the basis of the results of previous trials/studies in which the composition of this formulation had been reported to be effective in treating flu symptoms and has shown immune booster activities.

Selection and Timing of Dose for Each Patient Oral administration

One tablet daily after break-fast or lunch for 28 days.

Blinding

Due to the objectives of the study, the identity of the test and control treatments were not be known to investigators, research staff or patients. The following study procedures were in place to ensure double-blind administration of study procedures.

- Access to the randomization code was strictly controlled.
- Packaging and labelling of test and control treatments will be identical to maintain the blind.
- The study blind was broken on completion of the clinical study and after the study data base has been locked.

For Clinical trial use only DailyTab™ Gold (Immuno Booster) or DailyTab™ Gold (Immuno Booster For cardiac, Diabetics and Neuro conditions) or Placebo Study code: PHAR/LNP/COVID19/2020/04 **Subject ID:** ---- Dosage: Once a day either at Morning or Afternoon FSSAI lic no: Batch no:LC0H143 Mfgdt: 08/2020 Exp dt:18 months from Mfg Study drug should be stored by the study site at controlled room temperature, 15 to 30ºC (59 to 86ºF). **Name of Sponsor name & Address:** LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)	**For Clinical trial use only** DailyTab™ Gold(Immuno Booster) or DailyTab™ Gold (Immuno Booster For cardiac, Diabetics and Neuro conditions) or Placebo Study code: PHAR/LNP/COVID19/2020/04 **Subject ID:** --- Dosage: Once a day either at Morning or Afternoon FSSAI lic no: Batch no:LC0L031 Mfgdt: 08/2020 Exp. dt:18 months from Mfg Study drug should be stored by the study site at controlled room temperature, 15 to 30ºC (59 to 86ºF). **Name of Sponsor name & Address:** LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)	**For Clinical trial use only** DailyTab™ Gold (Immuno Booster) or DailyTab™ Gold (Immuno Booster For cardiac, Diabetics and Neuro conditions) or Placebo Study code: PHAR/LNP/COVID19/2020/04 **Subject ID:** ---- Dosage: Once a day either at Morning or Afternoon FSSAI lic no: Batch no: LC0H145 Mfg, dt: 08/2020 Expdt:18 months from Mfg Study drug should be stored by the study site at controlled room temperature, 15 to 30ºC (59 to 86ºF). **Name of Sponsor name & Address:** LIFECARE NEURO PRODUCTS LTD. 70/1 Dharampur, Sai Road, Near Export Promotion Zone Phase-II, Baddi - 173205, (Distt. Solan) Himachal Pradesh (India)

Prior and Concomitant Therapy

All concomitant medication and concurrent therapies were documented at baseline/screening and on study Days 1 to Day 28 and at early termination when applicable. Dose, route, unit frequency of administration, and indication for administration and dates of medication were captured.

Treatment Compliance

Subjects were asked to keep a patient diary noting the day and date they started taking the study product and any adverse events. The patient diary was reviewed at each study visit and the note of all used and unused test product sachets were kept. Subjects had taken all medication over the duration of therapy in both Treatments who were considered compliant with the protocol therapy.

20. Efficacy and safety variables

Primary Efficacy Endpoint

- Clinical cure based on Clinician's assessment of symptoms (Time points – (Day 1, Day 7, Day 14 and Day 28).

Secondary Efficacy Endpoints

- Changes in RTPCR test results (Day 1, Day 14/Day 28)
- Clinical status as assessed by the 7-point ordinal Covid-19 scale (Day 1, Day 7, Day 14 and Day 28).
- Change in clinical laboratory findings
- Subject global assessment of symptoms
- Improvement in Blood Oxygen saturation levels
- Changes in chest finding using x-ray
- Necessity of invasive assisted ventilation
- Necessity of non-invasive assisted ventilation
- Intensive care unit admission
- Post-anesthesia care unit admission

- Hospital admission
- Medical consultation
- Home care and isolation time
- Bed rest time
- Subject's perception of recovery

Safety Evaluations

- Change in clinical laboratory findings to Day28
- Incidence of adverse events

Data Quality Assurance

The study was performed in compliance with ICH-GCP guidelines as required by the regulatory agencies and the ethical principles according to the Declaration of Helsinki and local legal and regulatory requirements. The study was monitored according to the ICH-GCP guidelines.

Sponsor QA, Study management and monitoring representatives of CRO conducted site visits, to ensure that the study was in line with GCP Guidelines and Regulations; the CRF's were completed correctly, that the protocol was adhered to, to monitor drug accountability, and to collect completed pages of the CRF. In order to perform their role, the monitor was given direct access to source documents (original documents, data and records). Direct access included permission to examine, analyze, verify and reproduce any record(s) and report(s) that are important to evaluate the clinical trial. Source documentation was reviewed by representatives from the CRO.

Statistical and analytical plans

Prior to the analysis of the final study data, a detailed Statistical Analysis Plan (SAP) was written describing all analyses that were performed.

Data SetsAnalyzed

All eligible patients who were included into the study and received at least one dose of the study product (the Safety Population) was included in the safety analysis.

Demographic and baseline characteristics

The demographic variables at screening were summarized by group: race, gender, age, height and weight.

Data Sets Analyzed

All eligible patients who were included into the study and received at least one dose of the study drug (the SafetyPopulation) will be included in the safety analysis.

Analysis of Endpoints

All the data were analysed using SAS 9.1 version. All data were expressed as mean ± SD or Percentage. Appropriate test was used for statistical analysis. A probability $p < 0.05$ was considered significant. Clinical Efficacy and Safety data were summarized by treatment group.

Safety analysis:

Safety analysis was performed, based on the safety population.
Safety endpoints include:

- Prevalence of AEs stratified by severity and frequency.
- Incidence of AEs associated with use of the study product/ Control group.
- Incidence of SAEs associated with use of the study product/ control group.
- Incidence of patients with at least one documented AE.
- Proportion of patients who stopped treatment due to AEs.

AE/SAE prevalence and number of patients with AEs/SAEs (percentage of safety analysis population) were calculated.

All the safety data were compared between the study groups.

To compare AE/SAE incidence in the treatment groups, χ^2 test was applied. To compare AE/SAE severity and possible casualty between AEs/SAEs, Mann–Whitney U test was applied.

Sample Size

A total number of 45 subjects were involved in the study.

Sample size justification:

The sample size was calculated based on the assumption that the minimum expected clinical difference (mean score) considered was 20% and the standard deviation in the population in which the trial was undertaken was 15. Thus the standardized difference equates to 1.0, and the type I and Type II errors were fixed at 5 and 20 (Alpha at 0.05 and 80% Power),it gave a sample size of 12 in each group and a total sample size of 36 patients were required to achieve the trial end points. Considered the 20% drop out of subjects, a total of 45 subjects were required to meet the trial end points.

21. Study Patients

Disposition of Patients

Out of 54 patients that were screened, 9 were found screen failures. 5 patients of screen failures were severe covid-19 patients, 2 subjects were withdrawn consents and 2 subjects were shifted to ICU. Remaining 45 patients were assigned to treatment allocation as per randomization along with standard treatment.

Table 3: Patient disposition details

S. No	Variable	Disposition details
1.	No. of subjects screened for study	54
2.	No. of subjects screen failure	9
3.	Reason for screen failure	
	Severe Covid-19	5
	ICU	2
	Consent withdrawn	2
4.	No. of subjects enrolled in the study	45
5.	No. of subjects randomized in DailyTab™ Gold (Immuno Booster) + Standard treatment group.	15
6.	No. of subjects randomized in Placebo+Standard treatment group	15
7.	No. of subjects randomized in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group	15
8.	No. of subjects that completed the day 28(visit 3) in DailyTab™ Gold (Immuno Booster) + Standard treatment group	15
9.	No. of subjects that had completed the day 28 (visit 4) in Placebo+ Standard treatment group	15
10.	Number of subjects that had completed the day 28 (visit 4) in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group.	15

Protocol deviations:

There were no protocol deviations were reported.

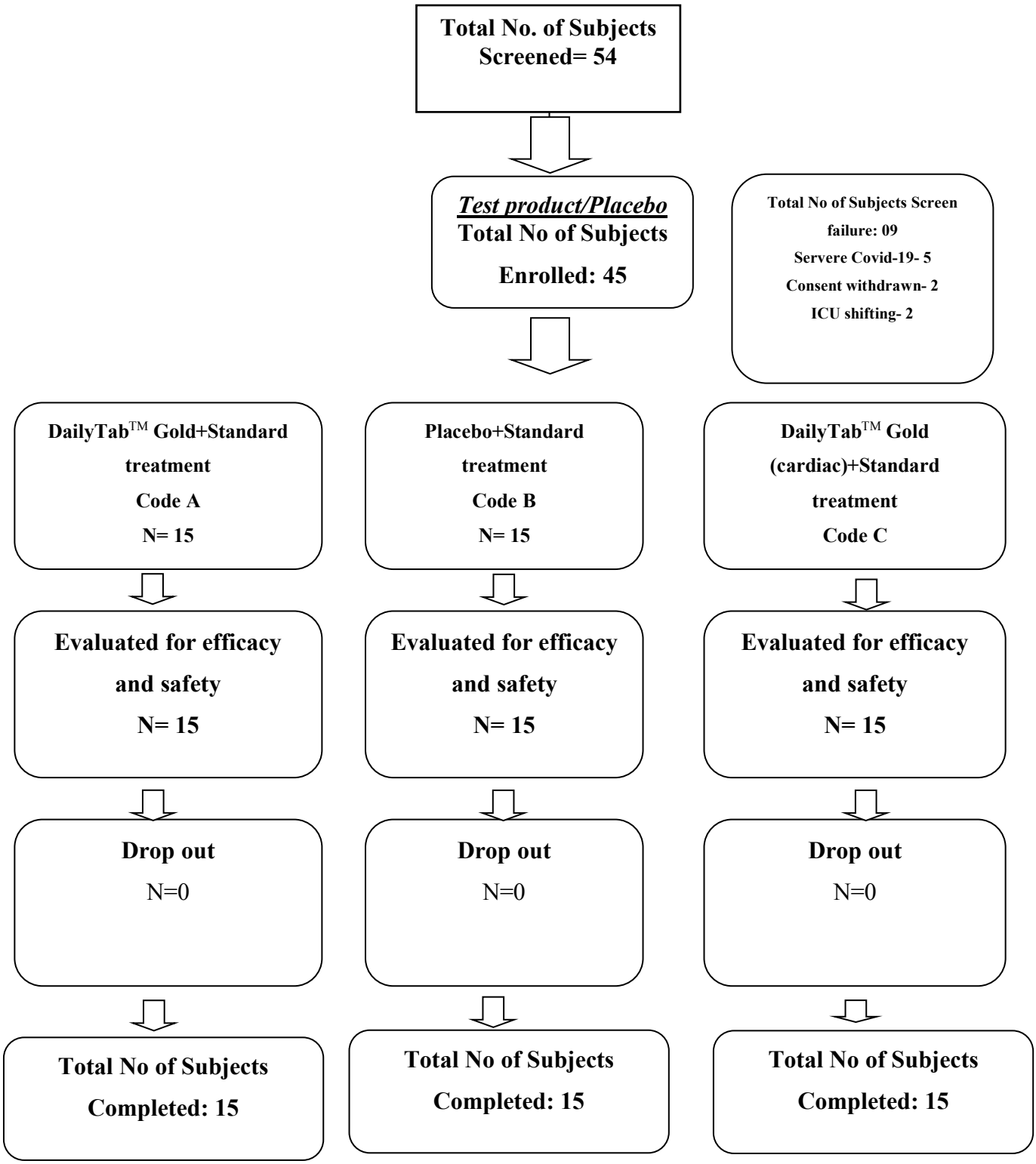
Study dates and schedules:

S. No	Schedule	Dates
1.	First subject ICF date	06 Jan 2021
2.	Last subject ICF date	30 Jan 2021
3.	First subject screening date	06 Jan 2021
4.	Last subject screening start date	30 Jan 2021
5.	Date of first subject randomization date	06 Jan 2021
6.	Date of Last subject randomization	30 Jan 2021
7.	Date of first subject completed day 7 visit	12 Jan 2021
8.	Date of Last subject completed day 7 visit	05 Feb 2021
9.	Date of first subject completed day 14 visit	18 Jan 2021
10.	Date of Last subject completed day 14 visit	14 Feb 2021
11.	Date of first subject completed day 28 visit	02 Feb 2021
12.	Date of Last subject completed day 28 visit	01 Mar 2021

Center wise distribution of patients:

S. No	Site Details	Name of PI	No. of patients enrolled
01	Rajalakshmi Hospital & Research center Lakshmipura Main Road, Vidyaranyapura Banglore-560097 Bangalore, Karnataka, India	Dr. Giriraja K V Consultant- General Medicicne	45

Disposition of Patients



22. Efficacy Results

Data sets analyzed

Table 4: Data sets analysed

Treatments	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)	Placebo + Standard treatment (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)
Enrolled	15	15	15
No. of subjects randomized in each group	15	15	15
No. of subjects assessed for efficacy and safety at baseline (Day 0)	15	15	15
No. of subjects assessed for efficacy and safety at Day 7	15	15	15
No. of subjects assessed for efficacy and safety at Day 14	15	15	15
No. of subjects assessed for efficacy and safety at Day 28	15	15	15
No. of subjects assessed for efficacy and safety at Day 35	15	15	15
Number of subjects withdrawn	0	0	0

Number of subjects drop out	0	0	0

Demographics:

The mean age of the subjects were 37, 38.14 and 39.47 years in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster for cardiac, Diabetic and Neuro conditions) + Standard treatment group.

The mean height of the subjects were 166.07, 163.86 and 164.60 cm in DailyTab™ Gold (Immuno Booster) + Standard treatment group Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster for cardiac, Diabetic and Neuro conditions) + Standard treatment group.

The mean weight of the subjects were 74.69, 73.82 and 73.9 kg in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster for cardiac, Diabetic and Neuro conditions) + Standard treatment group.

The mean BMI of the subjects were 27.08, 27.54 and 27.29 kg/m^2 in DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment.

Table 5: Demographic characteristics

S. No.	Demographics	Variable	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)	Placebo + Standard treatment (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)	P-value
1.	Age	Mean	37.00	38.14	39.47	0.65
		SD	14.24	12.63	12.19	
		Min	23.00	21.00	20.00	
		Max	64.00	64.00	64.00	
2.	Height	Mean	166.07	163.86	164.60	0.43
		SD	4.22	3.78	5.04	
		Min	159.00	159.00	153.00	
		Max	172.00	170.00	172.00	
3.	Weight	Mean	74.69	73.82	73.90	0.23
		SD	7.53	8.71	5.34	
		Min	63.00	58.00	62.00	
		Max	88.30	86.00	82.50	
4.	BMI	Mean	27.08	27.54	27.29	0.56
		SD	2.54	3.55	1.83	
		Min	23.43	21.3	24.05	
		Max	31.28	32.36	30.76	

Other Demographic variables:

In total 45 subjects, 28 subjects were male subjects and 17 subjects were females. In DailyTab™ Gold (Immuno Booster) + Standard treatment 11 were males and 4 were females. In placebo treatment 5 were males and 10 were females. In DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment 12 were males and 3 were females.

Table 6: Other Demographic variables

S. No	Variables	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)	Placebo + Standard treatment (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)	P-value
1.	Sex				
	a. Male	11	5	12	0.17
	b. Female	4	10	3	
2.	Race & Ethnicity				
	a. Asian and Indian	15	15	15	-
	b. Other	0	0	0	-
3.	Marital Status				
	a. Married	11	13	12	0.65
	b. Not married	4	2	3	

Vital signs at screening:

There were no significant differences between the vitals blood pressure, body temperature, respiratory rate and body temperature between the groups at baseline.

Table 7: Vital signs at screening between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment groups.

S. No	Vital signs	Variable	DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment (N=15)	Placebo + Standard treatment (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)
1.	Systolic BP (mmhg)	**Mean**	124.07	123.57	122.27
		SD	9.51	5.72	8.61
		Min	110.00	110.00	110.00
		Max	150.00	130.00	142.00
2.	Diastolic BP (mmhg)	**Mean**	82.27	82.86	81.47
		SD	4.33	3.82	6.91
		Min	78.00	78.00	70.00
		Max	90.00	90.00	96.00
3.	Pulse Rate /bpm	**Mean**	87.60	82.50	86.00
		SD	8.53	5.10	9.83
		Min	76.00	76.00	74.00
		Max	104.00	96.00	112.00
4.	Respiratory Rate /min	**Mean**	20.20	18.36	19.36
		SD	1.74	1.15	1.69
		Min	18.00	17.00	17.00
		Max	23.00	21.00	22.00

5.	Body Temperature	**Mean**	101.91	101.39	101.49
		SD	1.14	0.92	1.04
		Min	99.40	99.90	99.40
		Max	103.60	103.10	103.20

Pre-existing conditions and medications

In DailyTab™ Gold (Immuno Booster) + Standard treatment group, pre-existing medical conditions were hysterectomy, diabetes mellitus and hypertension. In Placebo + Standard treatment group, pre-existing medical conditions were hypothyroidism, diabetes mellitus and hypertension. In DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) + Standard treatment, pre-existing medical conditions were hypothyroidism, and hypertension.

DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15) group:

Table 8: Pre-existing conditions and medication history in DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15).

S. No.	Pre-existing condition	Medication	Dosage	Frequency	Duration
1.	Hysterectomy	NIL	NIL	Hysterectomy	Ongoing
2.	Diabetes Mellitus	Metformin	2gm-BD-oral	Diabetes Mellitus	Ongoing
3.	Hypertension	Telma-AM	OD-oral	Hypertension	Ongoing

Placebo + Standard treatment

Table 9: Pre-existing conditions and medication history in Placebo + *Standard treatment (N=15)*

S. No.	Pre-existing condition	Medication	Dosage	Frequency	Duration
1.	Hypothyroidism	Thyronorm	75mcg-OD-oral	Hypothyroidism	Ongoing
2.	Diabetes Mellitus	Metformin	2gm-BD-oral	Diabetes Mellitus	Ongoing
3.	Hypertension	Telma-AM	OD-oral	Hypertension	Ongoing

DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment (N=15)

Table 10: Pre-existing conditions and medication history in DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) + Standard treatment *(N=15)*

S. No.	Pre-existing condition	Medication	Dosage	Frequency	Duration
1.	Hypothyroidism	Thyronorm	75mcg-OD-oral	Hypothyroidism	Ongoing
2.	Hypertension	Telma-AM	OD-oral	Hypertension	Ongoing
3.	Hypertension	Amlodipine	5 mg OD-oral	Hypertension	Ongoing

Baseline symptoms and standard treatment:

There were no significant difference between baseline symptoms and standard treatments given between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group.

Table 11: Baseline symptoms and standard treatments between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment groups.

S. No	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)		Placebo + Standard treatment		DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)	
	Baseline covid 19 symptoms	Medications with Dose and	Baseline covid 19 symptoms	Medications with Dose and	Baseline covid 19 symptoms	Medications with Dose and

		Frequency and route		Frequency and route		Frequency and route
001	High grade fever, chills, nausea, vomiting, cold, sneeze, cough	1.Paracip-650mg-TDS-oral 2.PansecDSR-40mg-BD-oral 3.HCQ's-200mg-OD-oral 4.Azee-500mg-BD-oral	Fever, Cough, Sore throat, smell-lessness, tastelessness,tiredness, Diabetes Mellitus.	1.Metformin-2gm-BD-oral 2.Dolo-650mg-TDS-oral 3.Novomox-CV—625mg-BD-oral 4.HCQ-400mg-OD-oral	High fever with chills, tastelessness, smell-lessness, cough with sputum, sore throat, tiredness	1.Dolo-650mg-TDS-oral 2.MoxikindCV-650mg-BD-oral 3.MontekLC-15mg-BD-Oral
002	High grade fever, chills, dyspnea, cold, cough, headache, tiredness	1.Paracip-650mg-TDS-oral 2.MontekLC-15mg-BD-Oral 3.Amoxicillin-625mg-BD-oral 4.HCQ's-200mg-BD-oral	Hypothyroidism, fever, cold, cough, sneeze, headache, joint pain	1.Thyronorm-75mcg-OD-oral 2. Dolo-650mg-TDS-oral 3.Pansec-40mg-BD-oral 4. Azee-500mg-BD-oral 5. HCQ's-200mg-BD-oral	Fever, Cough, Gastritis	1.Paracetamol-650mg-IV-TID 2.Augmentin-1.2g-BD-IV 3.Pansec-40mg-BD-IV
003	Fever Cough	1.Dolonest-650mg-TID-Oral 2.HCQ's-200mg-BD-Oral 3.Azee-500mg-BD-Oral	Running nose Cough Fever	1.Ebast-DC-10mg-oral-BD 2.Megamox-CV-625mg-BD-oral 3.Dolo-625mg-oral-TID	Fever Cough	1.Paracetamol-100mg-TID-IV 2.HCQ's-400mg-BD-oral 3.Piptaz-4.5g-TID-IV 4.NEbulization-TID-Nasal
004	Fever Cough	1.Dolo-650mg-TID-oral 2.Azee-500mg-BD-oral 3.Budecort-BD-Nasal	Fever Cough	1.Calpol-650mg-TID-oral 2.AmoxCV-625mg-BD-oral 3.HCQ's-200mg-BD-oral	Fever Gastritis Cough	1.Dolo-650mg-TID-Oral 2.PANSEC-40mg-BD-Oral 3.HCQ's-200mg-OD-oral 4.Azee-500mg-BD-oral
005	Fever Cough Cold	1.Calpol-650mg-TID-oral 2.HCQ's-400mg-BD-oral 3.Azee-500mg-BD-oral 4.EbastDC-15mg-BD-oral	Fever Cough Hypertension	1.Dolo-650mg-TID-oral 2.HCQ's-400mg-BD-oral 3.Augmentin-625mg-BD-oral 4.AlmokindAT-50/25-OD-oral	Fever Cough Running nose Cold	1.Arden-650mg-TID-oral 2.MoxikindCV-625mg-TID-oral 3.AllercetDC-15mg-BD-oral 4.HCQ's-400mg-BD-oral
006	Fever, Rhinorrhoea, headache, body ache, cough with sputum, 2 episodes of vomiting.	1.PansecDSR-40mg-BD-IV 2.Dolocip-100mg-TDS-IV 3.Piptaz-4.5g-BD-IV 4. HCQ-400mg-BD-oral	fever, cold, cough, shortness of breath, tiredness, loose stools.	1.Arden-600mg-TDS-oral 2.PanD-40mg-BD-oral 3.Sporlac-50mg-BD-oral 4.OF-02-400mg-BD-oral	K/C/O Hypertension, Fever, cold, breathlessness, cough, tiredness	1.Calpol-650mg-TDS-oral 2.Linizolid-600mg-BD-oral 3. HCQ-400mg-BD-oral 4.TelmaAM-OD-oral
007	K/C/O Hypertension, Diabetes Mellitus, fever, cold, cough, cough	1.GlycometGP1-BD1-oral 2.OlmatSR-40mg-OD-oral 3.Paracetamol-100mg-TID-IV	K/C/O Diabetes Mellitus, fever, cold, cough, sore throat, tiredness, joint pain.	1.Gemer-2gm-BD-oral 2. Calpol-650mg-TDS-oral 3.Augmentin-	Fever, cold, running nose, cough, backache, joint pain, Tiredness	1. Dolo-650mg-TDS-oral 2. Pansec-40mg-BD-oral 3. HCQ-200mg-BD-oral

	with sputum, throat pain, tiredness	4.Piptaz-4.5g-TID-IV 5.HCQ-400mg-OD-oral		625mg-BD-oral 4. Pansec-40mg-BD-oral 5.HCQ-400mg-OD-oral		4.CefiCV-200mg-BD-oral
008	Fever, cold, cough, running nose, headache, vomiting, tiredness.	1.Calpol-650mg-TDS-oral 2.Ebast-M-15mg-BD-oral 3.MonocefCV-250mg-BD-oral 4.HCQ-200mg-OD-oral	Fever, cold, cough, tiredness, weakness, sore throat, tastelessness, smell-lessness	1.Paracip-500mg-TDS-oral 2.Azee-500mg-BD-oral 3.HCQ-200mg-BD-oral	Fever, cold, running nose, sneeze, cough with sputum, headache, tiredness, gastritis	1.Dolo-650mg-TDS-oral 2.Novomox-CV—625mg-BD-oral 3.Pansec-40mg-BD-oral 4.HCQ-400mg-OD-oral
009	Fever Cough Gastritis	1.Arden-650mg-TID-IV 2.Piptaz-4.5g-TID-IV 3.Pansec-40mg-BD-IV 4.HCQ-200mg-OD-oral	Cough, cold, elevated temperature, tiredness, sore throat	1.Paracip-650mg-TDS-oral 2.Azee-500mg-BD-oral 3.HCQ-200mg-BD-oral	Fever Cough Gastritis	1.Dolo-650mg-TID-oral 2.Cefi-IV-200mg-BD-Oral 3.Pansec-40mg-BD-oral
010	Cough Fever Gastritis	1.Piptaz-4.5g-TID-IV 2.Paracip-1g-TID-IV 3.Pansec-40mg-BD-IV 4.HCQ's-400mg-OD-oral 5.Remidisivir-100mg-OD-IV	Fever Cough	1.Paracip-650mg-tid-oral 2.Azee-500mg-bd-oral 3.HCQ-200MG-BD-oral	Fever Gastritis Cough	1.Calpol-650mg-TID-oral 2.Pansec-40mg-BD-oral 3.HCQ-200mg-OD-oral 4.Megamox-CV-625mg-BD-oral
011	Fever Cough Sore throat Loss of taste Loss of smell Joint pain	1.Dolo-650 mg-TDS-ORAL 2.Citi-cv-200 mg-BD-oral 3.Pansec-40 mg-BD-oral	Fever Cough Cold	1.Calpol-650mg-TID-oral 2.HCQ's-400mg-BD-oral 3.Monocef-250mg-BD-oral 4.EbastDC-15mg-BD-oral	Fever Cough Running nose Headache Vomiting Tiredness cold	1.Calpol-650mg-TDS Oral 2.monocef-250mg-BD-oral 3.HCQ-200mg-OD-ORAL 3.Enas (2-M)-150mg-BD-oral
012	Fever Cough Cold Body pain tiredness	1.Calpol-650mg-tid-oral 2.Pansec-40mg-bd-oral 3.HCQ-20 MG-OD-oral 4.Megaur ox-CV-625mg-bd-oral	Fever Cough Cold	1.Calpol-650mg-TID-oral 2.HCQ's-200mg-BD-oral 3.NovomoxCV-625mg-BD-oral 4.EbastDC-15mg-BD-oral	Fever Cold Cough Headache Tiredness Loss of smell	1.Paraaiden-650 mg-TID-iv-oral 2.Pansec-40mg-bd-iv 3.Piptaz-4.5 gm-iv 4. H1-200MG-od-oral
013	Cough Fever Gastritis	1.Piptaz-4.5g-TID-IV 2.Paracip-1g-TID-IV 3.pansel-40mg-BD-IV 4.HCQ's-200mg-OD-oral	Fever Cold Cough Shortness of breath Tiredness Loose stools	1.Arden-600mg-tid-ora 2.Pan-D-40mg-bd-oral 3.Spoclac-50mg-bd-oral 4.OF-02-BD-oral	Fever Cough Gastritis	1.Dolo-650mg-TID-oral 2.ZifiCV-200mg-BD-oral 3.Pansec-40mg-BD-oral 4.HCQ's-400mg-OD-oral
014	Fever Cough	1.Piptaz-4.5gm-tid-iv	Fever Cold	1.Dolo650mg-tid-oral	Fever Sore throat	1.Dolo-650mg-tid-oral

	Chest pain General weakness fatigue	2.Paracip-1gm-tid-iv 3.Pansec-40mg-bd-iv 4.HCQ-40mg-od-oral 5.Remdesvir-100mg-od-iv	Cough Loss of smell Loss of taste Tiredness headache	2.Azee-500mg-bd-oral	Loss of taste Loss of smell Joint pain cough	2.Cefi-cv-200mg-bd-oral 3.Pansec-40mg-bd-oral
015	Fever Chill Cough Loss of smell Joint pain Loss of taste	1.Dolo-650mg-tid-ora 2.Cefi-CV-200MG-BD-oral 3.Pansec-40mg-bd-oral	Fever, cold, cough, tiredness, weakness, sore throat, tastelessness, smell-lessness	1. Dolo650mg-tid-oral ,Paracip-500mg-TDS-oral 2.Azee-500mg-BD-oral 3.HCQ-200mg-BD-oral	Fever Cough Chest pain general weakness fatigue	1.Piptaz-4.5gm-tid-iv 2.Paracip-1gm-tid-iv 3.Pansec-40mg-bd-iv 4.MCR-40 mg-bd-oral 5.Remdesevir-100mg-bd-oral

Treatment compliance

One tablet once daily after breakfast or lunch. All subjects were treatment compliant for 28 days of treatment along with their standard treatment.

Table 12: Treatment compliance

Subject number	Number of units dispensed	Number of units used	Number of units returned	Remarks
1.	28 Tablets	28 Tablets	0	Compliant
2.	28 Tablets	28 Tablets	0	Compliant
3.	28 Tablets	28 Tablets	0	Compliant
4.	28 Tablets	28 Tablets	0	Compliant
5.	28 Tablets	28 Tablets	0	Compliant
6.	28 Tablets	28 Tablets	0	Compliant
7.	28 Tablets	28 Tablets	0	Compliant
8.	28 Tablets	28 Tablets	0	Compliant
9.	28 Tablets	28 Tablets	0	Compliant
10.	28 Tablets	28 Tablets	0	Compliant

11.	28 Tablets	28 Tablets	0	Compliant
12.	28 Tablets	28 Tablets	0	Compliant
13.	28 Tablets	28 Tablets	0	Compliant
14.	28 Tablets	28 Tablets	0	Compliant
15.	28 Tablets	28 Tablets	0	Compliant
16.	28 Tablets	28 Tablets	0	Compliant
17.	28 Tablets	28 Tablets	0	Compliant
18.	28 Tablets	28 Tablets	0	Compliant
19.	28 Tablets	28 Tablets	0	Compliant
20.	28 Tablets	28 Tablets	0	Compliant
21.	28 Tablets	28 Tablets	0	Compliant
22.	28 Tablets	28 Tablets	0	Compliant
23.	28 Tablets	28 Tablets	0	Compliant
24.	28 Tablets	28 Tablets	0	Compliant
25.	28 Tablets	28 Tablets	0	Compliant
26.	28 Tablets	28 Tablets	0	Compliant
27.	28 Tablets	28 Tablets	0	Compliant
28.	28 Tablets	28 Tablets	0	Compliant
29.	28 Tablets	28 Tablets	0	Compliant
30.	28 Tablets	28 Tablets	0	Compliant
31.	28 Tablets	28 Tablets	0	Compliant
32.	28 Tablets	28 Tablets	0	Compliant
33.	28 Tablets	28 Tablets	0	Compliant

34.	28 Tablets	28 Tablets	0	Compliant
35.	28 Tablets	28 Tablets	0	Compliant
36.	28 Tablets	28 Tablets	0	Compliant
37.	28 Tablets	28 Tablets	0	Compliant
38.	28 Tablets	28 Tablets	0	Compliant
39.	28 Tablets	28 Tablets	0	Compliant
40.	28 Tablets	28 Tablets	0	Compliant
41.	28 Tablets	28 Tablets	0	Compliant
42.	28 Tablets	28 Tablets	0	Compliant
43.	28 Tablets	28 Tablets	0	Compliant
44.	28 Tablets	28 Tablets	0	Compliant
45.	28 Tablets	28 Tablets	0	Compliant

WHO 7 point ordinal scale

In DailyTab™ Gold (Immuno Booster) + Standard treatment group, 13 out of 15 subjects (86.67%) had no clinical or virological evidence of infection after treatment for 28 days. The clinical cure status was statistical significant compared to placebo in DailyTab™ Gold (Immuno Booster) + Standard treatment group (p value 0.0002)

In Placebo + Standard treatment group, 3 out of 15 subjects (6.67%) had no clinical or virological evidence of infection after treatment for 28 days.

In DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, 14 out of 15 subjects (93.33%) had no clinical or virological evidence of infection after treatment for 28 days. The clinical cure status was statistical significant compared to placebo in DailyTab™ Gold (Immuno Booster for cardiac,

Diabetic and Neuro conditions)+ Standard treatment groups (p value 0.0003) at 28 days of treatment.

Table 13: Clinical cure of subjects status on 7-point ordinal scale between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment groups.

Clinical Assesment	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)				Placebo+ Standard treatment (N=15)				DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment (N=15)				P-value*	P-value#
	Baseline	Day7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28	0.0004	0.0003
No Clinical or Virological evidence of infection	0	7	11	13	0	0	1	1	0	9	14	14		
Not hospitalized, no limitations on activities	1	4	4	2	1	3	4	7	4	3	1	1		
Not hospitalized, limitations on activities	14	4	0	0	14	12	10	7	11	3	0	0		
Hospitalized, not requiring supplemental Oxygen	0	0	0	0	0	0	0	0	0	0	0	0		
Hospitalized, requiring supplemental Oxygen	0	0	0	0	0	0	0	0	0	0	0	0		
Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation	0	0	0	0	0	0	0	0	0	0	0	0		
Death	0	0	0	0	0	0	0	0	0	0	0	0		

*P<0.05 statistically significant compared to placebo in *DailyTab™ Gold (Immuno Booster)* + Standard treatment group at 28 days of treatment using odd ratio.

# P<0.05 statistically significant compared to placebo in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group at 28 days of treatment using odd ratio.

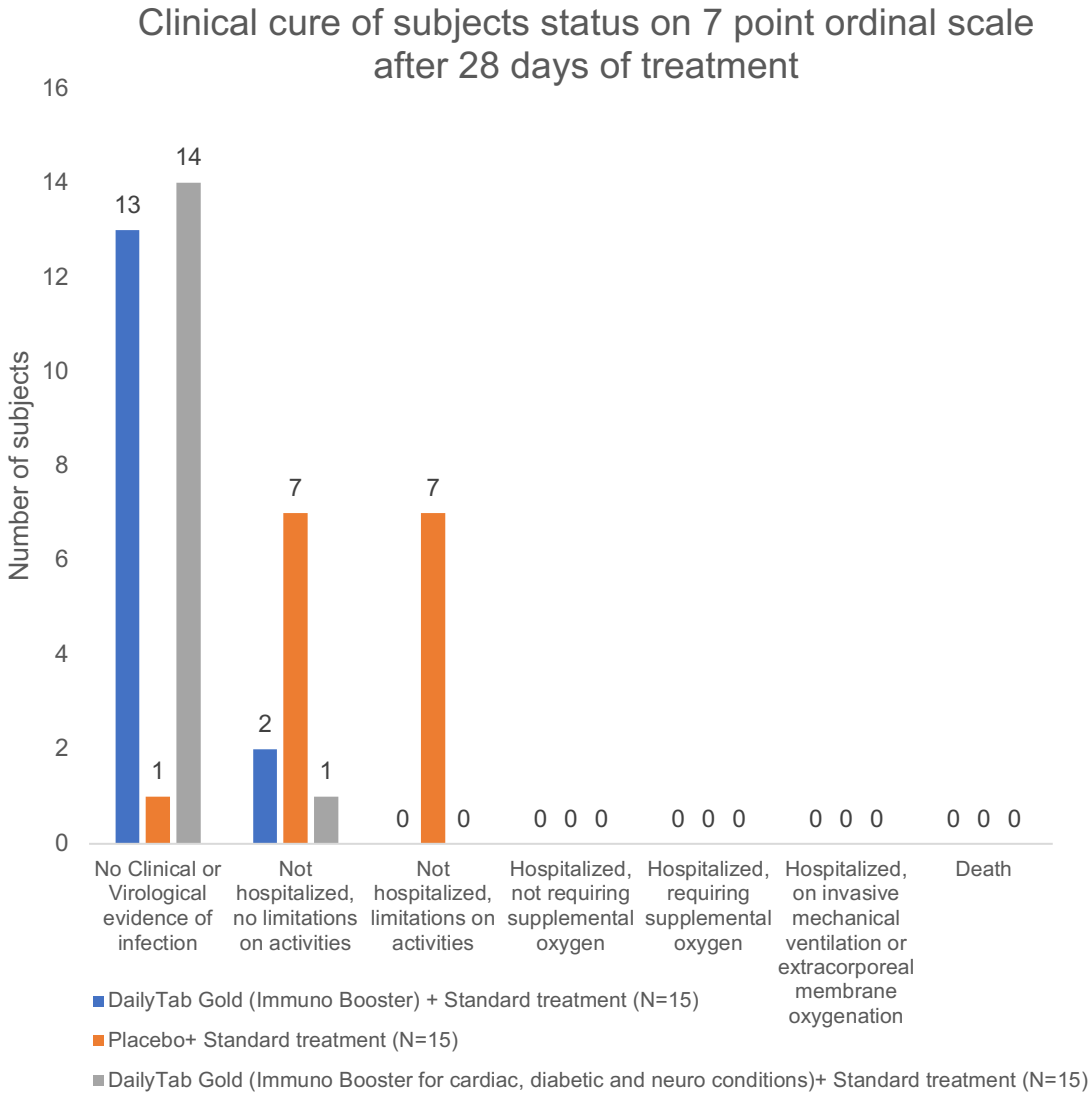


Figure 1: Clinical cure status of subjects on 7 point ordinal scale after 28 days of treatment

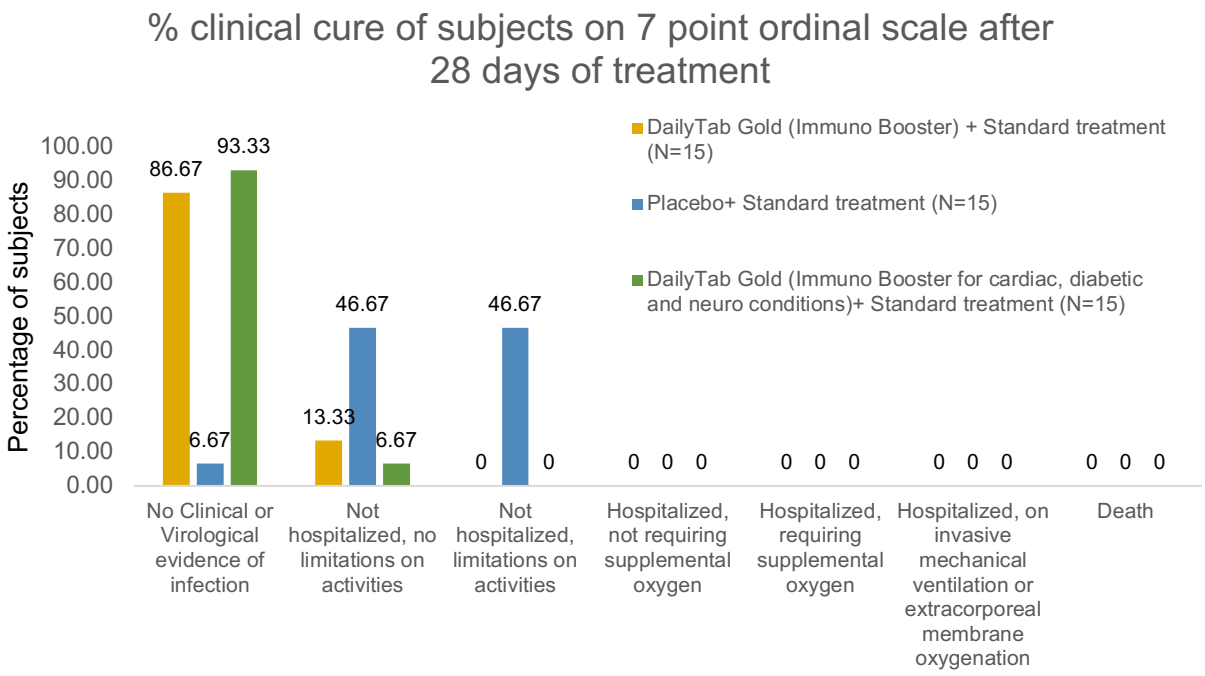


Figure 2: % Clinical cure of subjects on 7 point ordinal scale after 28 days of treatment.

RT-PCR test results

On day 14 post treatment, in DailyTab™ Gold (Immuno Booster) + Standard treatment group, 14 out of 15 subjects (93.33%) were virologically cured, in placebo +Standard treatment group 8 of 15 subjects (53.33%) were virologically cured and in DailyTab™Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, 100% subjects were virologically cured. The differences were statistical significant between the groups ($p<0.05$).

Table 14: Proportion of patients that had negative RT-PCR at Day 14 between the groups

Parameter	**DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment (N=15)**	**Placebo + Standard treatment (N=15)**	**DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment**	**Chi-square test***
Number of negative patients/total number of patients	14/15 (93.33%)	8/15 (53.33)	15/15 (100%)	0.004

*Statistically significant at $p<0.05$

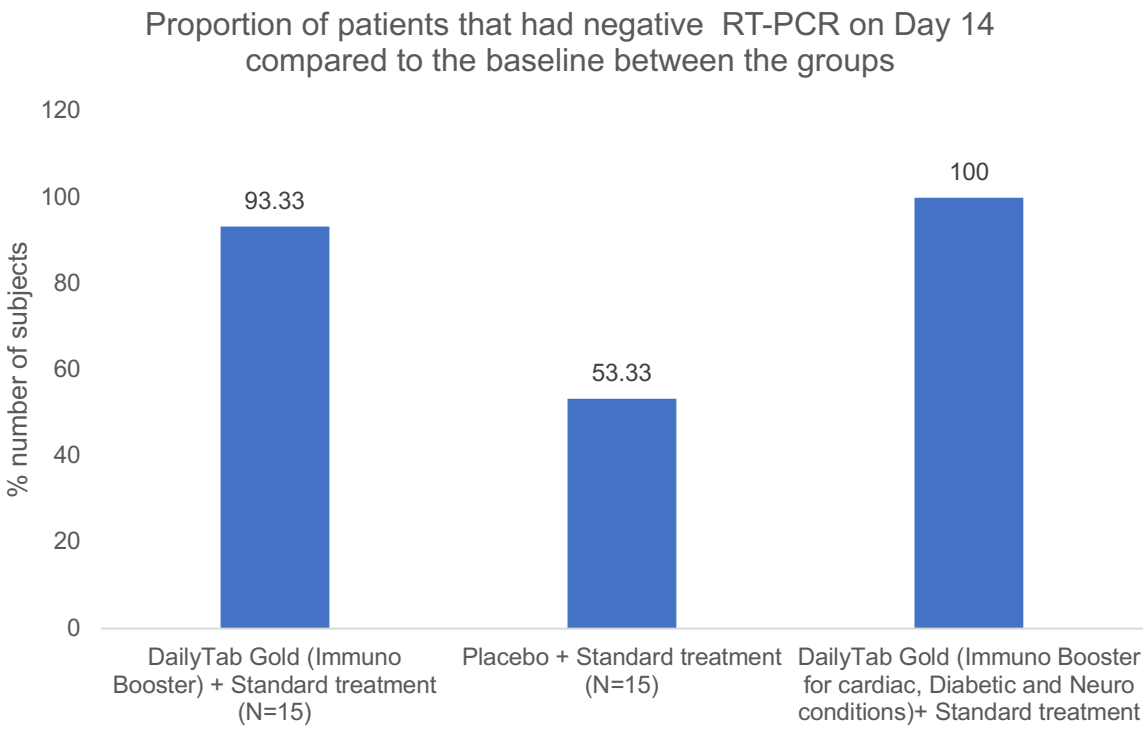


Figure 3: Proportion of patients that had negative RT-PCR compared to the baseline on Day 14.

Symptoms assessment

The disappearance rates (% of subjects) of clinical status of symptoms were high in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared with Placebo+standard treatment.

Table 15: Symptoms asessment between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Symptoms	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)					Placebo+ Standard treatment (N=15)				DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment (N=15)			
	Variables	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28
Cough	Nil	0	4	11	15	0	2	5	7	0	5	11	15
	Mild	0	11	4	0	0	11	10	8	6	10	4	0
	Moderate	15	0	0	0	15	2	0	0	9	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Fever with or without chill	Nil	0	11	15	15	0	3	6	9	0	12	15	15
	Mild	1	4	0	0	2	12	6	5	3	3	0	0
	Moderate	14	0	0	0	13	0	3	1	12	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Shortness of breath	Nil	0	7	15	15	0	2	6	8	2	8	13	15
	Mild	7	8	0	0	8	13	7	6	5	7	2	0
	Moderate	8	0	0	0	7	0	2	1	8	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Nasal congestion	Nil	0	13	15	15	0	5	11	11	0	15	13	15
	Mild	12	2	0	0	15	10	4	4	12	0	2	0
	Moderate	3	0	0	0	0	0	0	0	3	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
GI	Nil	4	14	15	15	6	8	9	11	7	15	15	15
	Mild	11	1	0	0	5	6	4	3	7	0	0	0

	Moderate	0	0	0	0	4	1	2	1	1	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Chest congestion	Nil	0	6	14	15	0	3	5	8	1	5	14	15
	Mild	10	9	1	0	13	12	10	7	13	10	1	0
	Moderate	5	0	0	0	2	0	0	0	1	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Anosmia	Nil	9	12	13	15	6	8	9	10	8	10	13	15
	Mild	6	3	2	0	6	5	4	5	5	5	2	0
	Moderate	0	0	0	0	3	2	2	0	2	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Diarrhea	Nil	8	15	14	15	6	8	10	11	10	14	15	15
	Mild	5	0	1	0	6	4	2	3	5	1	0	0
	Moderate	2	0	0	0	3	3	3	1	0	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Ageusia	Nil	7	12	13	14	8	9	9	10	14	11	13	15
	Mild	5	3	2	1	4	5	5	4	1	4	2	0
	Moderate	3	0	0	0	3	1	1	1	0	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Neuro disorders	Nil	8	15	14	15	14	15	15	11	11	14	14	14
	Mild	7	0	1	0	1	0	0	4	4	1	1	1
	Moderate	0	0	0	0	0	0	0	0	0	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Fatigue	Nil	8	14	15	15	11	12	13	14	14	14	15	15
	Mild	4	1	0	0	4	3	2	1	1	1	0	0
	Moderate	3	0	0	0	0	0	0	0	0	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Myalgia	Nil	3	3	8	15	3	3	9	10	3	7	13	15
	Mild	8	12	7	0	9	12	6	4	9	8	2	0
	Moderate	4	0	0	0	3	0	0	1	3	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Sleep disorder	Nil	9	15	15	15	8	8	9	10	10	14	15	15
	Mild	5	0	0	0	5	6	5	4	3	1	0	0
	Moderate	1	0	0	0	2	1	1	1	2	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0

Rhinorrhoea	Nil	8	12	14	15	7	8	10	11	8	12	15	15
	Mild	5	3	1	0	6	5	3	4	5	3	0	0
	Moderate	2	0	0	0	2	2	2	1	2	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Expectoration	Nil	1	6	12	15	0	4	8	8	4	6	11	15
	Mild	12	9	3	0	13	11	7	5	9	9	4	0
	Moderate	3	0	0	0	2	0	0	2	2	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Sore throat	Nil	1	6	15	15	1	1	6	8	1	7	15	15
	Mild	9	9	0	0	9	11	7	5	9	8	0	0
	Moderate	5	0	0	0	5	3	2	2	5	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
Vomiting	Nil	7	15	15	15	9	9	10	10	9	13	15	15
	Mild	5	0	0	0	4	5	3	4	4	2	0	0
	Moderate	3	0	0	0	2	1	2	1	2	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0
If Any Other Covid-19	Nil	1	7	9	15	1	2	7	8	4	7	10	15
	Mild	5	8	6	0	8	13	6	6	6	8	5	0
	Moderate	9	0	0	0	6	0	2	1	5	0	0	0
	Severe	0	0	0	0	0	0	0	0	0	0	0	0

Table 16: % Proportions of symptoms between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Symptoms	DailyTab Gold (Immuno Booster) + Standard treatment (N=15)					Placebo+ Standard treatment (N=15)				DailyTab Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment (N=15)			
	Variables	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28
Cough	Nil	0.0	26.66	73.3	100.0	0.0	13.3	33.3	46.7	0.0	33.3	73.3	100.0
	Mild	0.0	73.33	26.7	0.0	0.0	73.3	66.7	53.3	40.0	66.7	26.7	0.0
	Moderate	100.0	0.0	0.0	0.0	100.0	13.3	0.0	0.0	60.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Fever with or without chill	Nil	0.0	73.3	100.0	100.0	0.0	20.0	40.0	60.0	0.0	80.0	100.0	100.0
	Mild	6.7	26.7	0.0	0.0	13.3	80.0	40.0	33.3	20.0	20.0	0.0	0.0
	Moderate	93.3	0.0	0.0	0.0	86.7	0.0	20.0	6.7	80.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Shortness of breath	Nil	0.0	46.7	100.0	100.0	0.0	13.3	40.0	53.3	13.3	53.3	86.7	100.0
	Mild	46.7	53.3	0.0	0.0	53.3	86.7	46.7	40.0	33.3	46.7	13.3	0.0
	Moderate	53.3	0.0	0.0	0.0	46.7	0.0	13.3	6.7	53.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Nasal congestion	Nil	0.0	86.7	100.0	100.0	0.0	33.3	73.3	73.3	0.0	100.0	86.7	100.0
	Mild	80.0	13.3	0.0	0.0	100.0	66.7	26.7	26.7	80.0	0.0	13.3	0.0
	Moderate	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	20.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GI	Nil	26.7	93.3	100.0	100.0	40.0	53.3	60.0	73.3	46.7	100.0	100.0	100.0
	Mild	73.3	6.7	0.0	0.0	33.3	40.0	26.7	20.0	46.7	0.0	0.0	0.0
	Moderate	0.0	0.0	0.0	0.0	26.7	6.7	13.3	6.7	6.7	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Chest congestion	Nil	0.0	40.0	93.3	100.0	0.0	20.0	33.3	53.3	6.7	33.3	93.3	100.0
	Mild	66.7	60.0	6.7	0.0	86.7	80.0	66.7	46.7	86.7	66.7	6.67	0.0
	Moderate	33.3	0.0	0.0	0.0	13.3	0.0	0.0	0.0	6.7	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Anosmia	Nil	60.0	80.0	86.7	100.0	40.0	53.3	60.0	66.7	53.3	66.7	86.7	100.0
	Mild	40.0	20.0	13.3	0.0	40.0	33.3	26.7	33.3	33.3	33.3	13.3	0.0
	Moderate	0.0	0.0	0.0	0.0	20.0	13.3	13.3	0.0	13.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Diarrhea	Nil	53.3	100.0	93.3	100.0	40.0	53.3	66.7	73.3	66.7	93.3	100.0	100.0
	Mild	33.3	0.0	6.7	0.0	40.0	26.7	13.3	20.0	33.3	6.7	0.0	0.0
	Moderate	13.3	0.0	0.0	0.0	20.0	20.0	20.0	6.7	0.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Ageusia	Nil	46.7	80.0	86.7	93.3	53.3	60.0	60.0	66.7	93.3	73.3	86.7	100.0
	Mild	33.3	20.0	13.3	6.7	26.7	33.3	33.3	26.7	6.7	26.7	13.3	0.0
	Moderate	20.0	0.0	0.0	0.0	20.0	6.7	6.7	6.7	0.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Neuro disorders	Nil	53.3	100.0	93.3	100.0	93.3	100.0	100.0	73.3	73.3	93.3	93.3	93.3
	Mild	46.67	0.0	6.7	0.0	6.7	0.0	0.0	26.7	26.7	6.7	6.7	6.7
	Moderate	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Fatigue	Nil	53.3	93.3	100.0	100.0	73.3	80.0	86.7	93.3	93.3	93.3	100.0	100.0
	Mild	26.7	6.7	0.0	0.0	26.7	20.0	13.3	6.7	6.7	6.7	0.0	0.0
	Moderate	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Myalgia	Nil	20.0	20.0	53.3	100.0	20.0	20.0	60.0	66.7	20.0	46.7	86.7	100.0
	Mild	53.3	80.0	46.7	0.0	60.0	80.0	40.0	26.7	60.0	53.3	13.3	0.0
	Moderate	26.7	0.0	0.0	0.0	20.0	0.0	0.0	6.7	20.0	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Sleep	Nil	60.0	100.0	100.0	100.0	53.3	53.3	60.0	66.7	66.7	93.3	100.0	100.0

disorder	Mild	33.3	0.0	0.0	0.0	33.3	40.0	33.3	26.7	20.0	6.7	0.0	0.0
	Moderate	6.7	0.0	0.0	0.0	13.3	6.7	6.7	6.7	13.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Rhinorrhoea	Nil	53.3	80.0	93.3	100.0	46.7	53.3	66.7	73.3	53.3	80.0	100.0	100.0
	Mild	33.3	20.0	6.7	0.0	40.0	33.3	20.0	26.7	33.3	20.0	0.0	0.0
	Moderate	13.3	0.0	0.0	0.0	13.3	13.3	13.3	6.7	13.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Expectoration	Nil	6.7	40.0	80.0	100.0	0.0	26.7	53.3	53.3	26.7	40.0	73.3	100.0
	Mild	80.0	60.0	20.0	0.0	86.7	73.3	46.7	33.3	60.0	60.0	26.7	0.0
	Moderate	20.0	0.0	0.0	0.0	13.3	0.0	0.0	13.3	13.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Sore throat	Nil	6.7	40.0	100.0	100.0	6.7	6.7	40.0	53.3	6.7	46.7	100.0	100.0
	Mild	60.0	60.0	0.0	0.0	60.0	73.3	46.7	33.3	60.0	53.3	0.0	0.0
	Moderate	33.3	0.0	0.0	0.0	33.3	20.0	13.3	13.3	33.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Vomiting	Nil	46.7	100.0	100.0	100.0	60.0	60.0	66.7	66.7	60.0	86.7	100.0	100.0
	Mild	33.3	0.0	0.0	0.0	26.7	33.3	20.0	26.7	26.7	13.3	0.0	0.0
	Moderate	20.0	0.0	0.0	0.0	13.3	6.7	13.3	6.7	13.33	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
If Any Other Covid-19	Nil	6.7	46.7	60.0	100.0	6.7	13.3	46.7	53.3	26.7	46.7	66.7	100.0
	Mild	33.3	53.3	40.0	0.0	53.3	86.7	40.0	40.0	40.0	53.3	33.3	0.0
	Moderate	60.0	0.0	0.0	0.0	40.0	0.0	13.3	6.7	33.3	0.0	0.0	0.0
	Severe	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

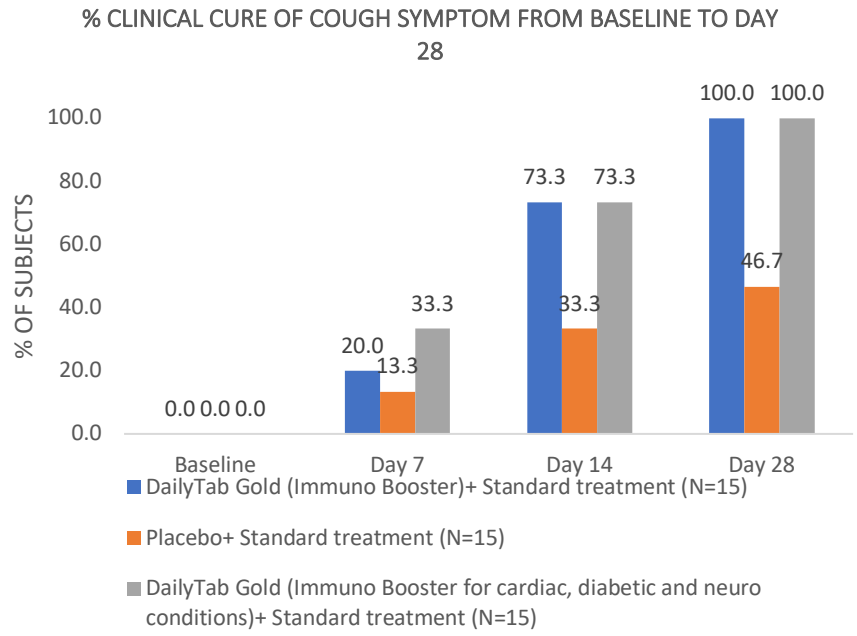


Figure 4: % Clinical cure of cough from baseline to day 28

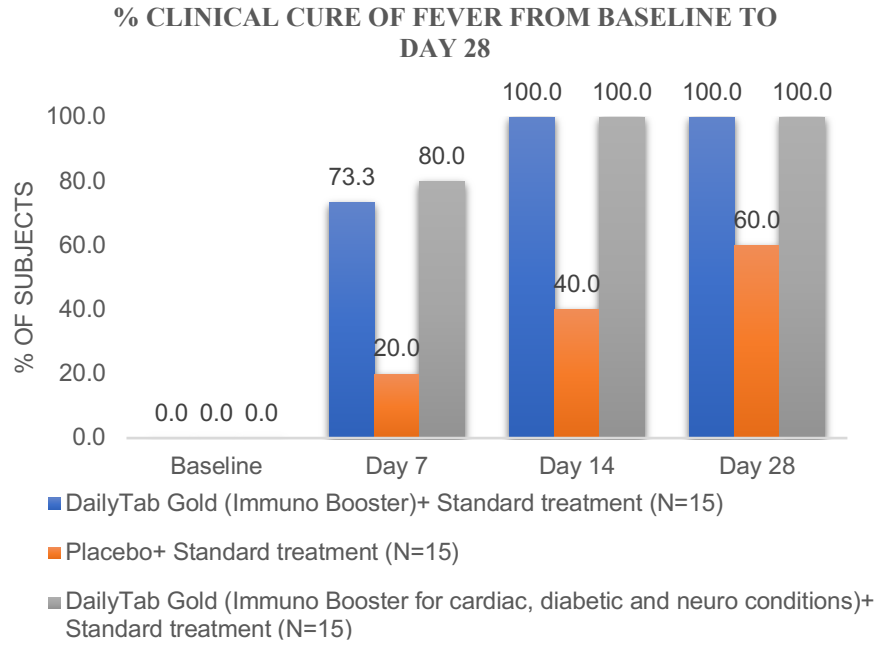


Figure 5: % Clinical cure of fever from baseline to day 28

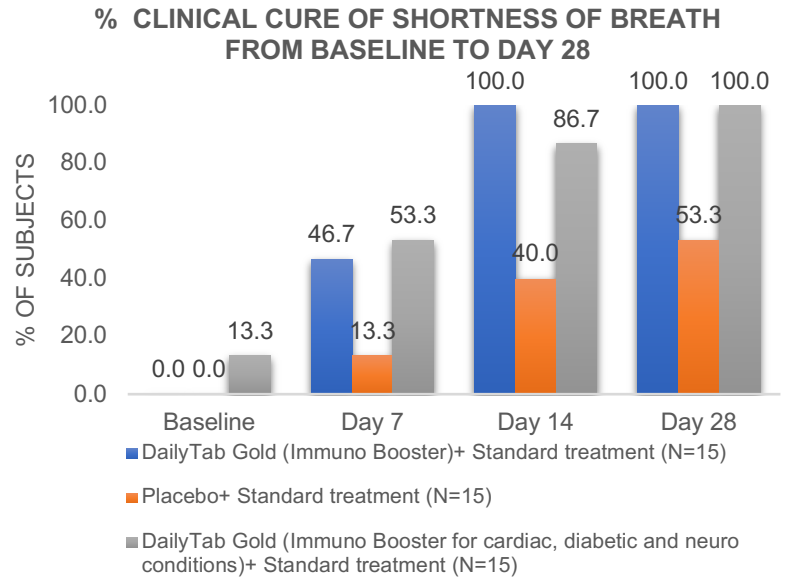


Figure 6: % Clinical cure of shortness of breath from baseline to day 28

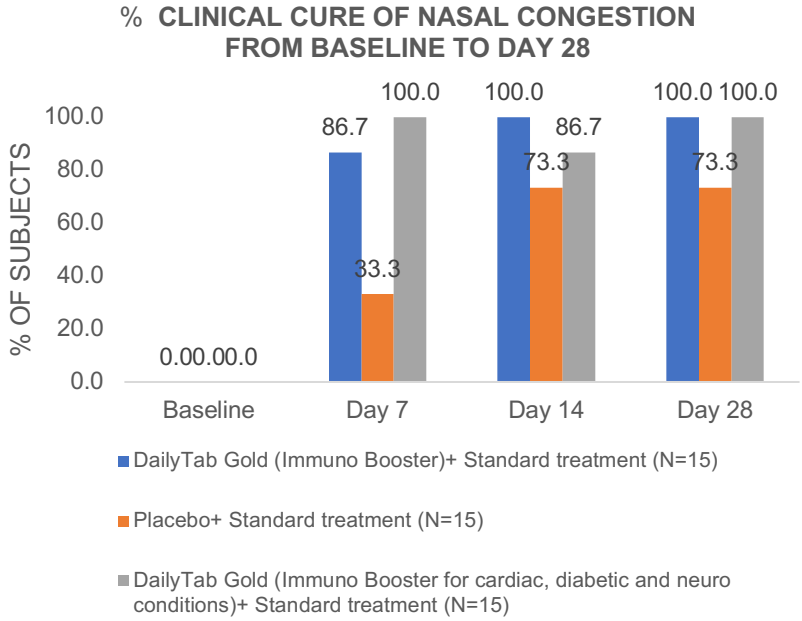


Figure 7: % Clinical cure of nasal congestion from baseline to day 28

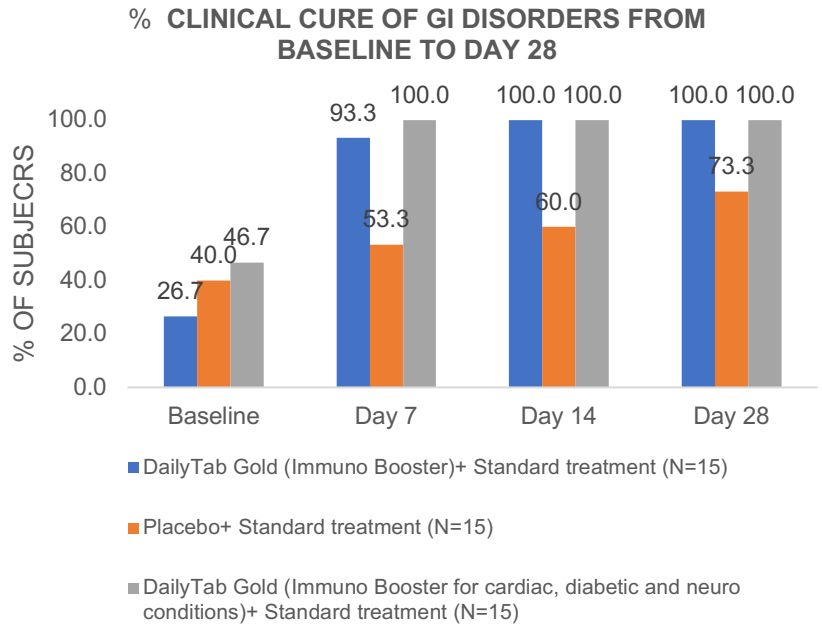


Figure 8: % Clinical cure of GI disorders from baseline to day 28

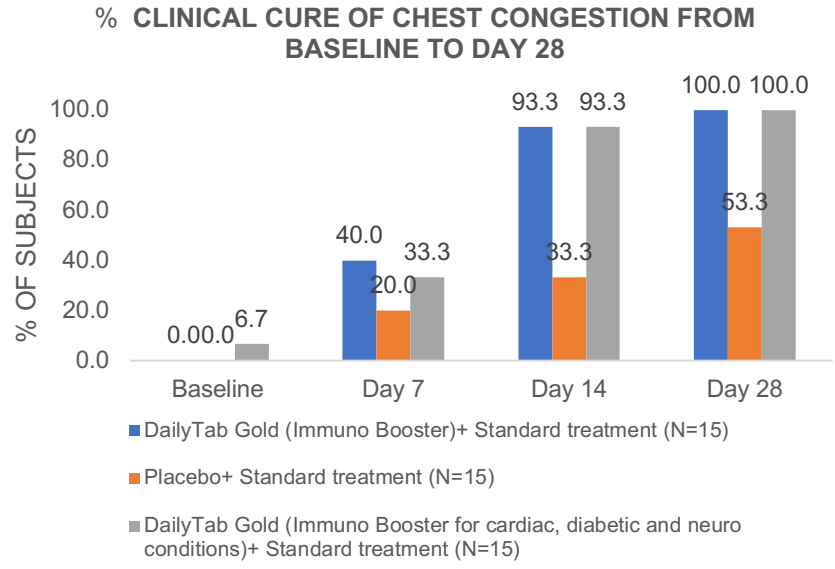


Figure 9: % Clinical cure of chest congestion from baseline to day 28

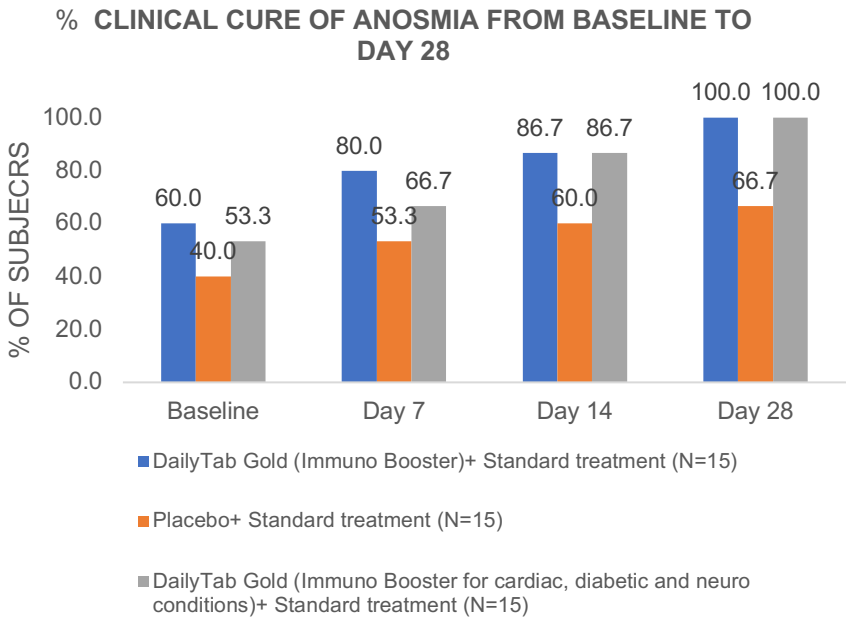


Figure 10: % Clinical cure of Anosmia from baseline to day 28

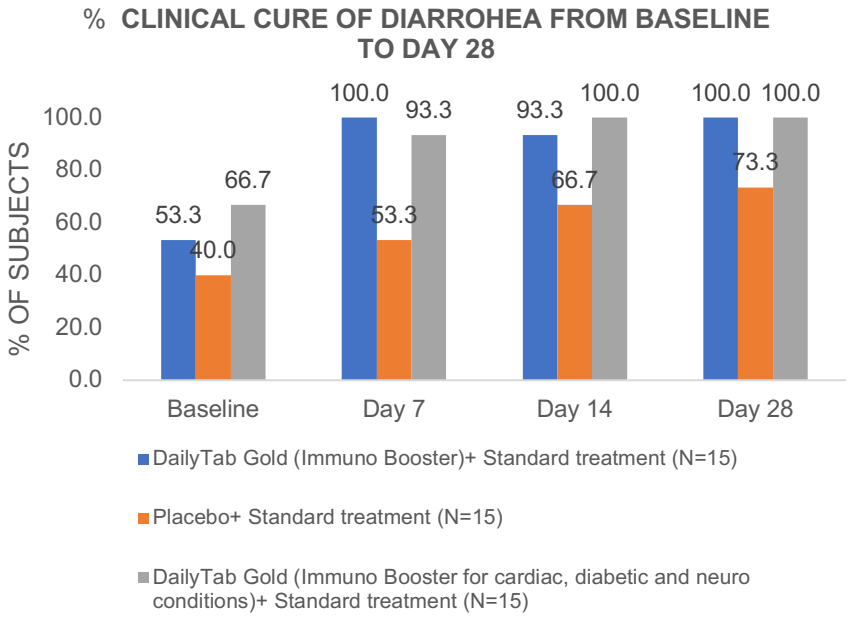


Figure 11: % Clinical cure of Diarrohea from baseline to day 28

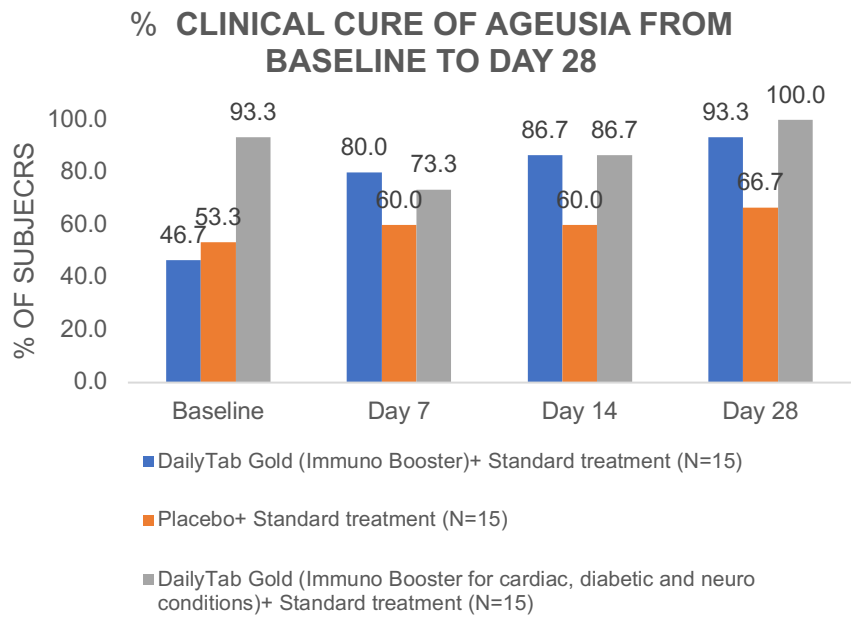


Figure 12: % Clinical cure of Ageusia from baseline to day 28

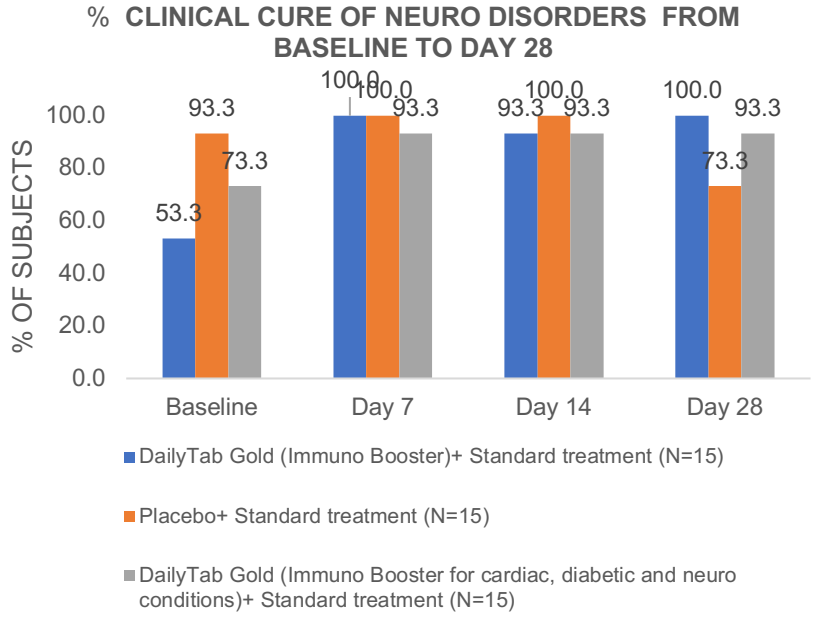


Figure 13: % Clinical cure of neuro disorders from baseline to day 28

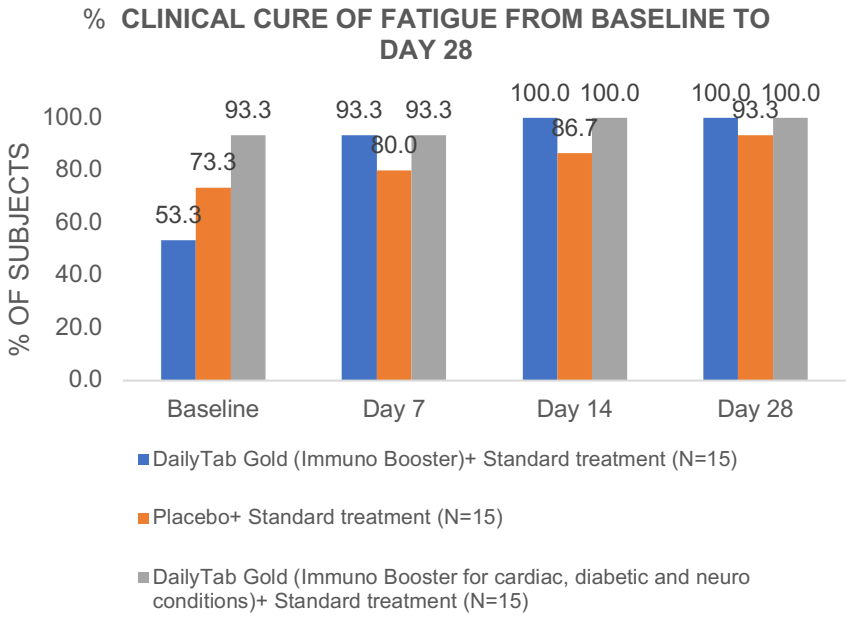


Figure 14: % Clinical cure of fatigue from baseline to day 28

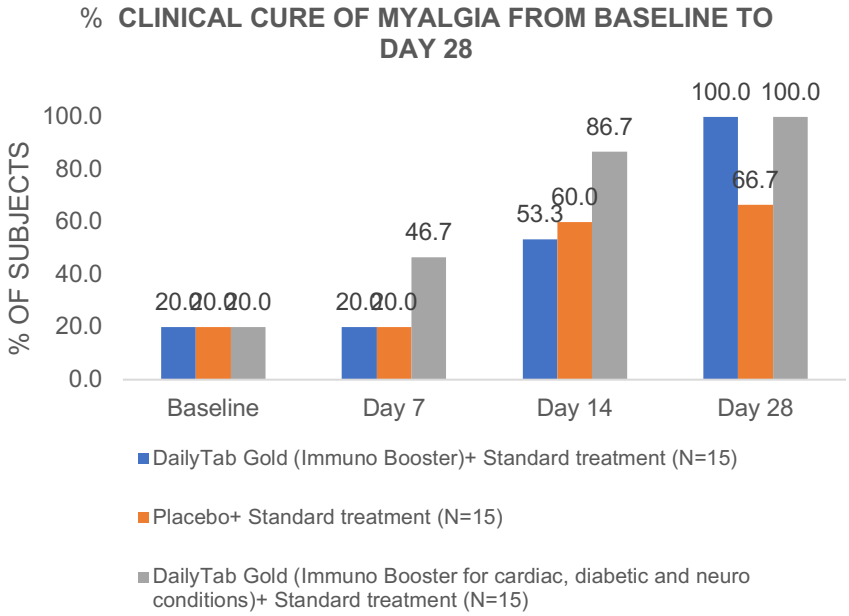


Figure 15: % Clinical cure of Myalgia from baseline to day 28

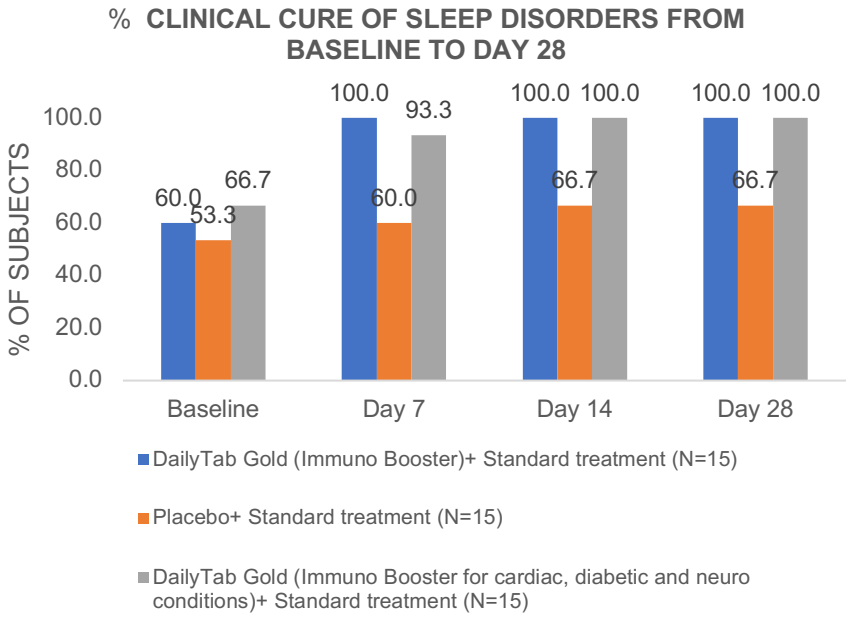


Figure 16: % Clinical cure of sleep disorders from baseline to day 28

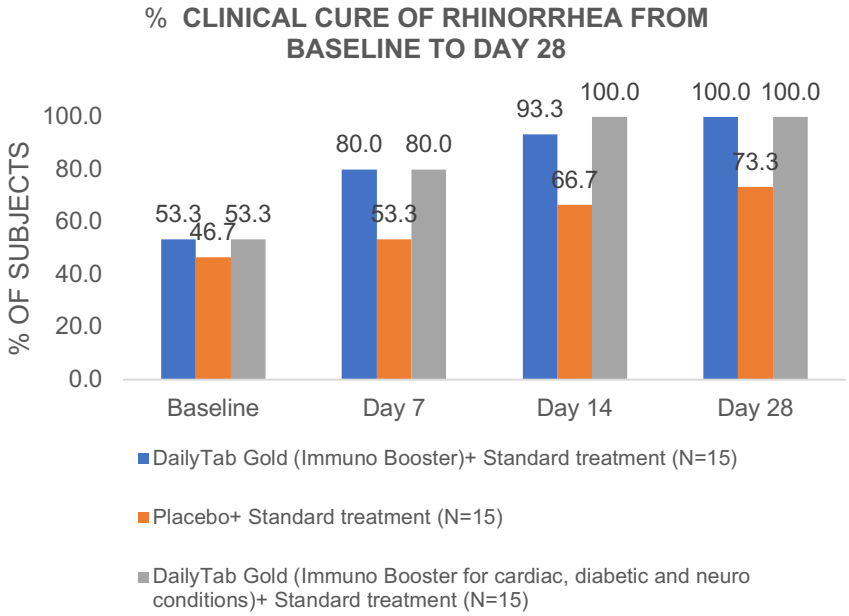


Figure 17: % Clinical cure of Rhinorrhea from baseline to day 28

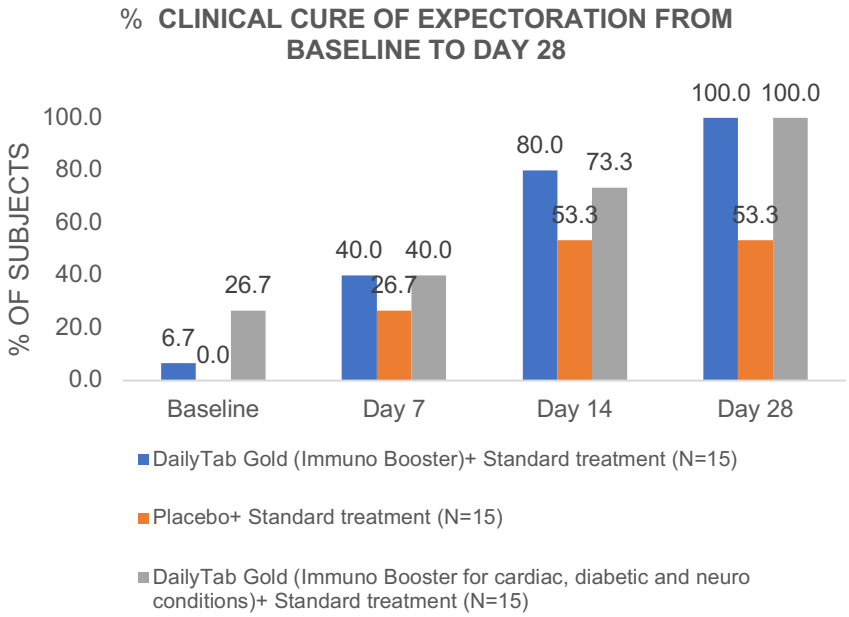


Figure 18: % Clinical cure of expectoration from baseline to day 28

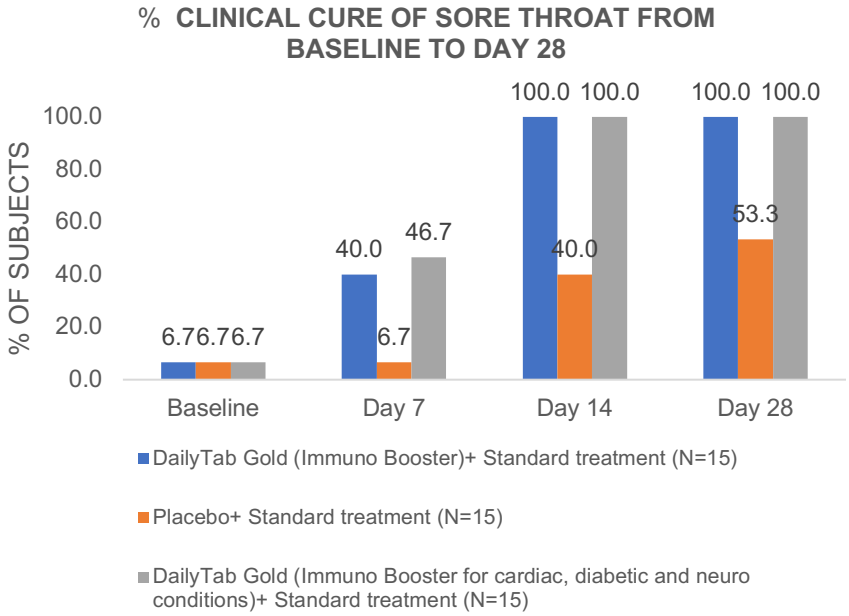


Figure 19: % Clinical cure of sore throat from baseline to day 28

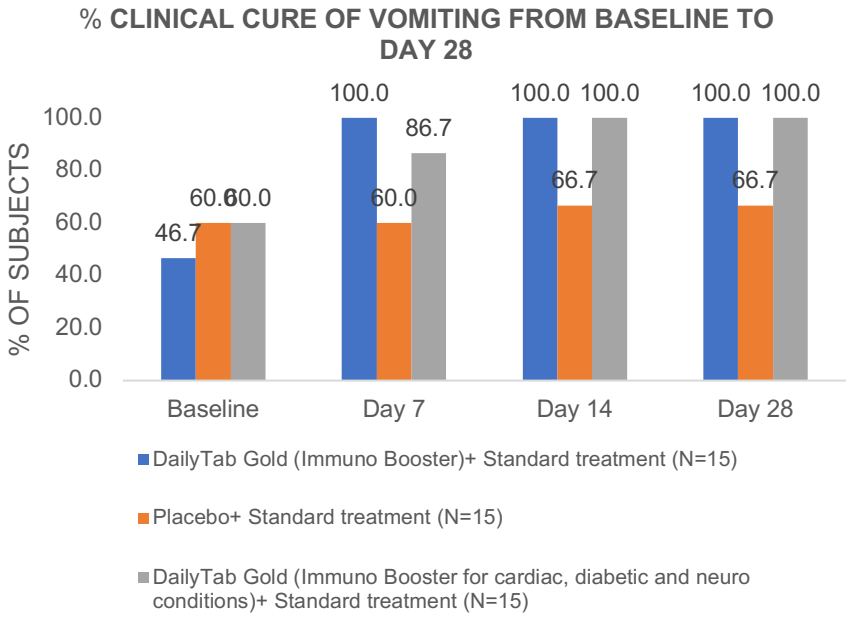


Figure 20: % Clinical cure of vomiting from baseline to day 28

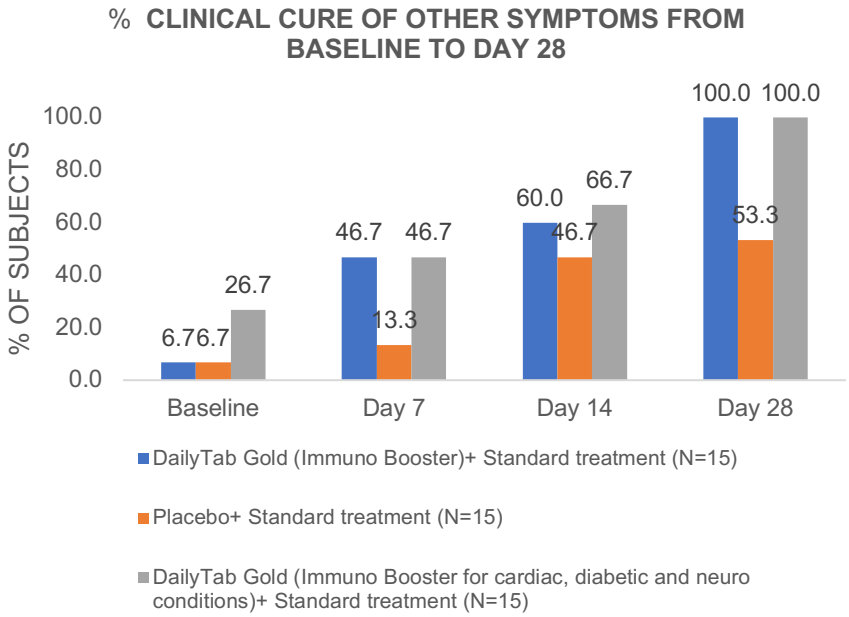


Figure 21: % Clinical cure of other symptoms from baseline to day 28

Symptom mean scores assessment

The mean scores of symptoms (in scale of Nil-0, Mild- 1, Moderate-2 and Severe- 3) assessed from Day 1 to Day 28 by subject questionnaire showed improvement in DailyTab™ Gold (Immuno Booster) + Standard treatment group when compared with day 1 scores and also when compared to the Placebo +Standard treatment.

Table 17: Subject mean scores of symptoms (Nil-0, Mild-1, Moderate-2 and severe-3) in DailyTab™ Gold (Immuno Booster) + Standard treatment group.

SYMPTOMS	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Fever with out chills	1.93	1.93	1.93	1.7	1.4	1	0.33	0.3	0.3	0.2	0	0	0	0
Nsasl congestion	1.8	1.8	1.47	1.3	0.8	0.5	0.27	0.1	0.1	0	0	0	0	0
Cough	2	2	1.93	1.5	1.4	1.1	0.53	0.5	0.5	0.4	0.13	0.1	0	0.1
Difficulty in breathing	1.93	1.93	1.53	1.1	0.7	0.5	0.33	0.3	0.3	0.2	0.07	0	0	0
Body Pains	1.93	1.93	1.67	1.5	1.4	0.9	0.6	0.6	0.6	0.5	0.53	0.2	0.1	0.1
GI	1.2	1.2	0.8	0.5	0.4	0.1	0	0	0	0	0	0	0	0
Headache	1.53	1.53	1.07	0.7	0.5	0.2	0.13	0.4	0.3	0.1	0	0	0	0
Fatigue	0.73	0.67	0.33	0.3	0.1	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Symptoms	Day 15	Day 16	Day 17	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28
Fever with out chills	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nsasl congestion	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cough	0.07	0.07	0	0	0	0	0	0	0	0	0	0	0	0
Difficulty in breathing	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Body Pains	0.07	0.07	0	0	0	0	0	0	0	0	0	0	0	0
GI	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Headache	0.07	0	0	0	0	0	0	0	0	0	0	0	0	0
Fatigue	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table 18: Subject mean scores of symptoms (Nil-0, Mild-1, Moderate-2 and severe-3) in Placebo + Standard treatment group

Symptoms	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Fever with out chills	2	2	2	1.86	1.6	1	0.9	0.7	0.6	0	0	0	0	0
Nasal congestion	1.86	2	2	1.57	1.1	1	0.7	0.8	0.8	0.2	0.1	0	0	0
Cough	1.86	2	2	1.71	1.4	1.14	0.9	0.9	0.9	0/3	0.5	0.4	0.36	0.4
Difficulty in breathing	1.86	2	1.79	1.21	0.9	0.71	0.3	0.8	0.7	0.4	0	0	0	0
Body Pains	2	1.93	1.79	1.36	1.1	0.93	0.7	0.9	0.9	0.9	0.8	0.7	0.29	0.3
GI	0.29	0.29	0.29	0.29	0.1	0.14	0	0	0	0	0	0	0	0
Headache	1.86	1.79	1.64	1.21	0.9	0.71	0.5	0.8	0.8	0.6	0.5	0.3	0.07	0.1
Fatigue	0	0	0	0	0	0	0	0.1	0.1	0.1	0.1	0.1	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Symptoms	**Day 15**	**Day 16**	**Day 17**	**Day 18**	**Day 19**	**Day 20**	**Day 21**	**Day 22**	**Day 23**	**Day**	**Day 25**	**Day 26**	**Day 27**	**Day 28**
Fever with out chills	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nasal congestion	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cough	0.5	0.5	0.43	0.36	0.3	0.31	0.3	0.3	0.3	0.1	0.2	0.2	0.23	0.2
Difficulty in breathing	0.5	0.43	0.43	0.25	0.3	0.29	0.3	0.3	0.3	0.2	0.2	0.1	0.14	0.1
Body Pains	0.64	0.64	0.57	0.45	0.5	0.43	0.4	0.4	0.4	0.3	0.3	0.2	0.07	0.1
GI	0.07	0.07	0.07	0.09	0.1	0.07	0.1	0.1	0	0	0	0	0	0
Headache	0.14	0.14	0.07	0.09	0.1	0.07	0.1	0.1	0.1	0.1	0.1	0	0	0
Fatigue	0.07	0.07	0.07	0.09	0.1	0.07	0	0	0	0	0	0.1	0.07	0.1
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

The mean scores of symptoms (in scale of Nil-0, Mild- 1, Moderate- 2 and Severe- 3) assessed from Day 1 to Day 28 by subject questionnaire showed improvement in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared with day 1 scores and also when compared to the Placebo +Standard treatment.

Table 19: Subject mean scores of symptoms (Nil-0, Mild-1, Moderate-2 and severe-3) in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Symptoms	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14
Fever with out chills	2	2	2	1.67	1.2	0.67	0.27	0.27	0.27	0.07	0	0	0	0
Nasal congestion	1.87	1.8	1.4	1.07	0.8	0.27	0.2	0.27	0.27	0.13	0	0	0	0
Cough	2	2	2	1.4	1.2	0.93	0.47	0.53	0.53	0.47	0.2	0.2	0.13	0.2
Difficulty in breathing	2	1.93	1.47	1	0.73	0.4	0.2	0.27	0.27	0.2	0	0	0	0
Body Pains	2	2	1.67	1.27	1.13	0.87	0.6	0.67	0.6	0.4	0.4	0.3	0.07	0.07
GI	0.67	0.67	0.47	0.4	0.33	0.07	0.07	0	0	0	0	0	0	0
Headache	1.67	1.67	1.07	0.8	0.6	0.4	0.2	0.4	0.33	0.2	0.1	0.1	0.07	0
Fatigue	0.73	0.67	0.4	0.33	0.2	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Symptoms	**Day 15**	**Day 16**	**Day 17**	**Day 18**	**Day 19**	**Day 20**	**Day 21**	**Day 22**	**Day 23**	**Day 24**	**Day 25**	**Day 26**	**Day 27**	**Day 28**
Fever with out chills	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nasal congestion	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cough	0.27	0.27	0	0	0	0	0	0	0	0	0	0	0	0
Difficulty in breathing	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Body Pains	0.43	0.43	0.43	0.4	0.43	0.43	0.36	0.36	0.27	0.27	0	0	0	0
GI	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Headache	0.27	0	0	0	0	0	0	0	0	0	0	0	0	0
Fatigue	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Other	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Chest X-ray assessment

Chest X-ray was performed in all of the enrolled patients at baseline and after 28 days of treatment. 13 out of 15 subjects had improved chest x-ray results in DailyTab™ Gold (Immuno Booster) + Standard treatment group and 14 out of 15 subjects had improved the chest x-ray results in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to 7 out of 15 patients improved in Placebo + standard treatment group. The results were statistically significant when compared to the placebo+standard treatment for both groups.

86.67 and 93.33 % of patients had improved the pulmonary results in chest x-ray in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to 46.67% of patients in Placebo + standard treatment group.

Table 20: Improvement in chest X-ray image results between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group

Chest X-ray	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)		Placebo+ Standard treatment (N=15)		DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)		P-value	P-value
	Baseline	Day 28	Baseline	Day 28	Baseline	Day 28		
Number of subjects had normal chest X-ray improvement	0	13	0	7	0	14	0.02*	0.01#
% of subjects had normal chest x-ray imrovement	86.67		46.67		93.33			

*P<0.05, significant for DailyTab™ Gold (Immuno Booster) + Standard treatment when compared to the Placebo+ Standard treatment group.
# P<0.05, significant for DailyTab™ Gold (Immuno Booster for cardiac, Diabetic and Neuro conditions) + Standard treatment when compared to the Placebo+ Standard treatment group.

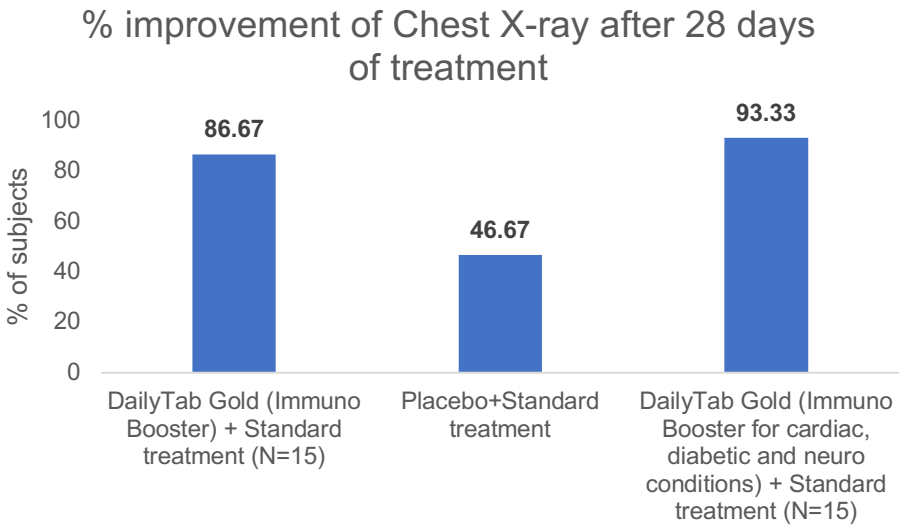


Figure 22: % improvement of chest x-ray image results compared to baseline

Hs-CRP evaluation

Novel corona virus (2019-CoV) increases C- reactive protein levels significantly, due to inflammatory reaction and related tissue destruction. Higher concentration indicates more severe disease linked to lung damage and worse prognosis.

The change rate of Hs-C reactive protein was favourable to DailyTab™Gold (Immuno Booster) + Standard treatment group and DailyTab™Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to placebo and standard treatment.

The mean results of Hs-CRP values (mg/L) at baseline were 103.95, 88.04 and 78.06 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group. After 28 days of treatment were 3.35, 75.14 and 15.61 mg/L respectively. The change in values were statistically significant when compared to baseline and also when compared to Placebo at Day 28.

Table 21: Hs-CRP values at Baseline and day 28 between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

HS-CRP	**DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)**		**Placebo+ Standard treatment (N=15)**		**DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)**		**P-value***	**P-value#**
	Baseline	**Day 28**	**Baseline**	**Day 28**	**Baseline**	**Day 28**		
Mean (mg/L)	103.95	3.35	88.04	75.14	78.06	15.61	0.0001	0.0001
SD	119.69	1.40	70.29	66.09	100.60	33.61		
% change of Hs-CRP values compared to baseline	-96.77		-14.65		-80.0			

*P<0.05, significant for DailyTab™ Gold (Immuno Booster) + Standard treatment when compared to the Placebo+ Standard treatment group.

# P<0.05, significant for DailyTab™ Gold (Immuno Booster for cardiac, Diabetic and Neuro conditions) + Standard treatment when compared to the Placebo+ Standard treatment group.

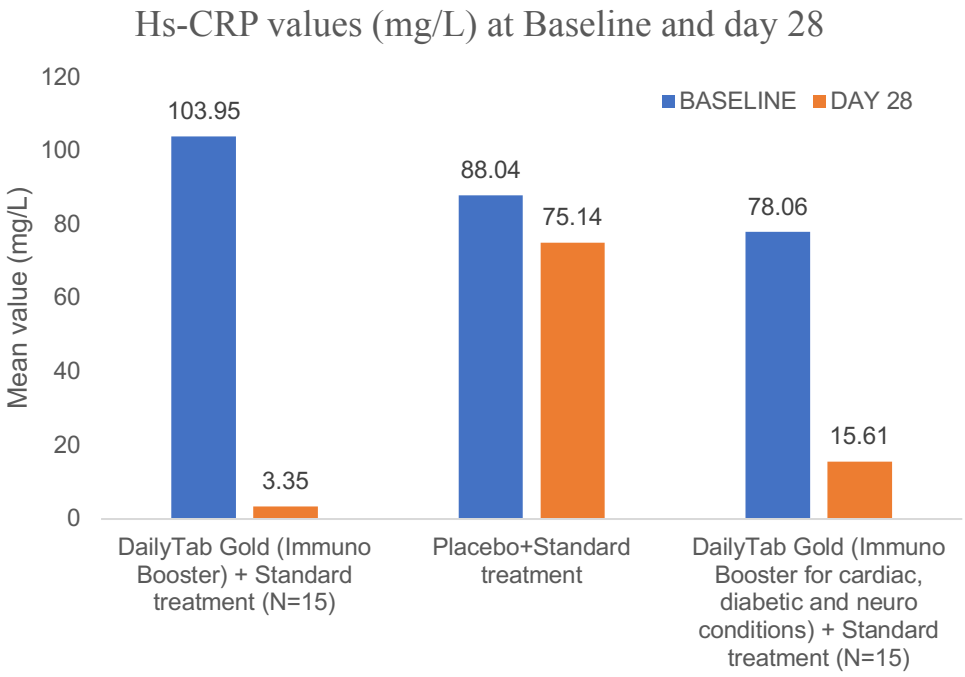


Figure 23: Hs-CRP values (mg/L) at Baseline and Day 28

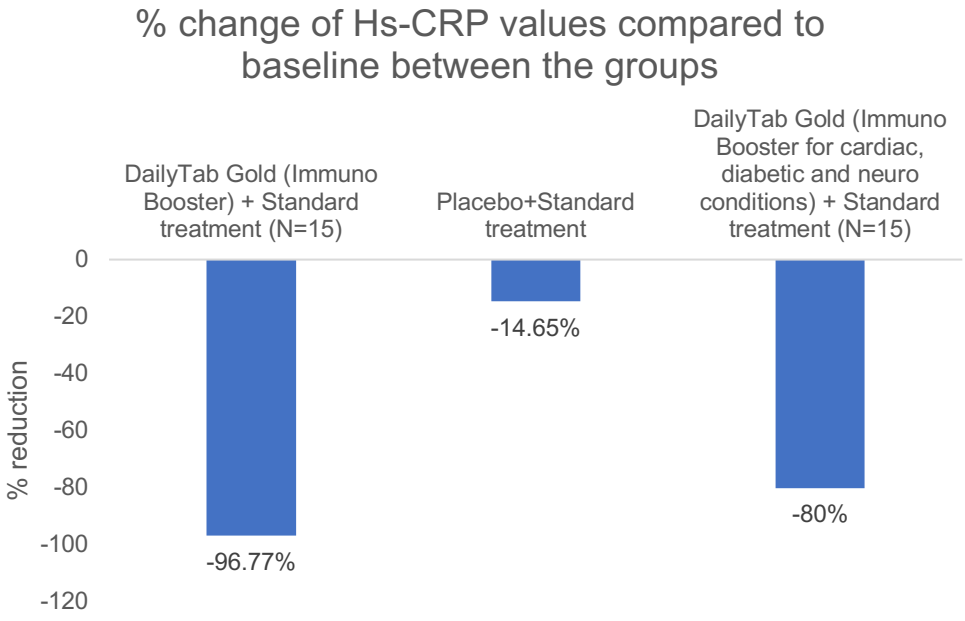


Figure 24: % change of Hs- CRP values (mg/L) compared to baseline

IL-6 (pg/mL) evaluation

At baseline, the mean values of IL-6 values were 20.6, 19.17 and 20.49 pg/mL in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, respectively. After treatment for 28 days, the values were 4.87, 22.13 and 4.21, respectively.

The % change of IL-6 was -76.36%, 15.44% and -79.45% for DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, respectively. The results were significant at P<0.05.

Table 22: IL-6 values (pg/mL) at baseline and Day 28 between DailyTab™Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Interleukin-6 (pg/mL)	DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15)		Placebo+ Standard treatment group (N=15)		DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group (N=15)		P-value*	P-value#
	Base line	Day 28	Base line	Day 28	Baseline	Day 28	0.001	0.001
Mean	20.60	4.87	19.17	22.13	20.49	4.21		
SD	9.91	1.47	8.43	22.13	9.56	1.93		

Table 23: % change of IL-6 values at Day 28 between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Lab Tests	Variable	DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15)	Placebo+ Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group (N=15)
IL-6 (pg/mL)	Percent change	-76.36	15.44	-79.45

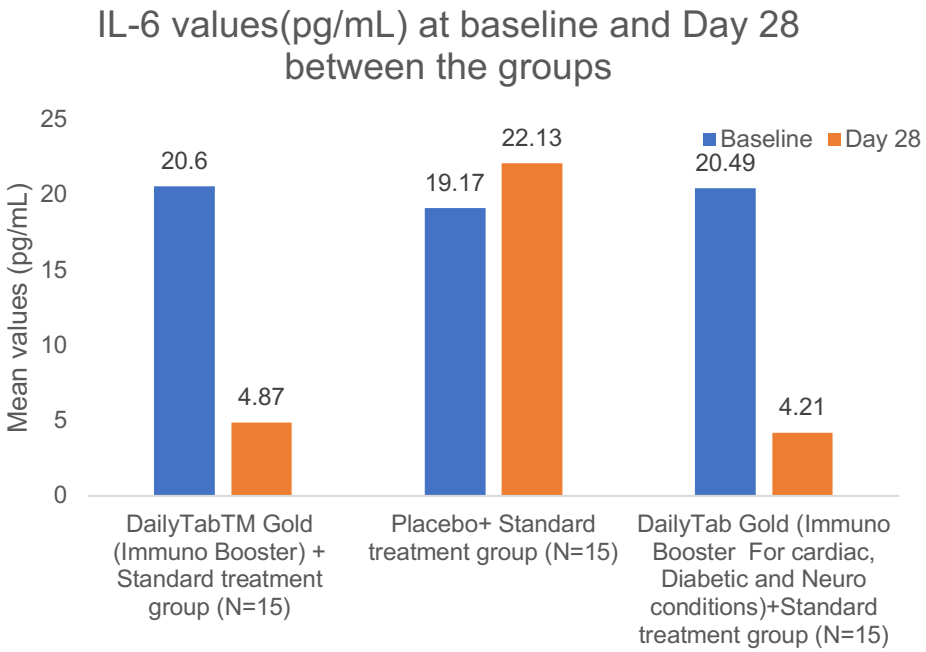


Figure 25: IL-6 values at baseline and Day 28.

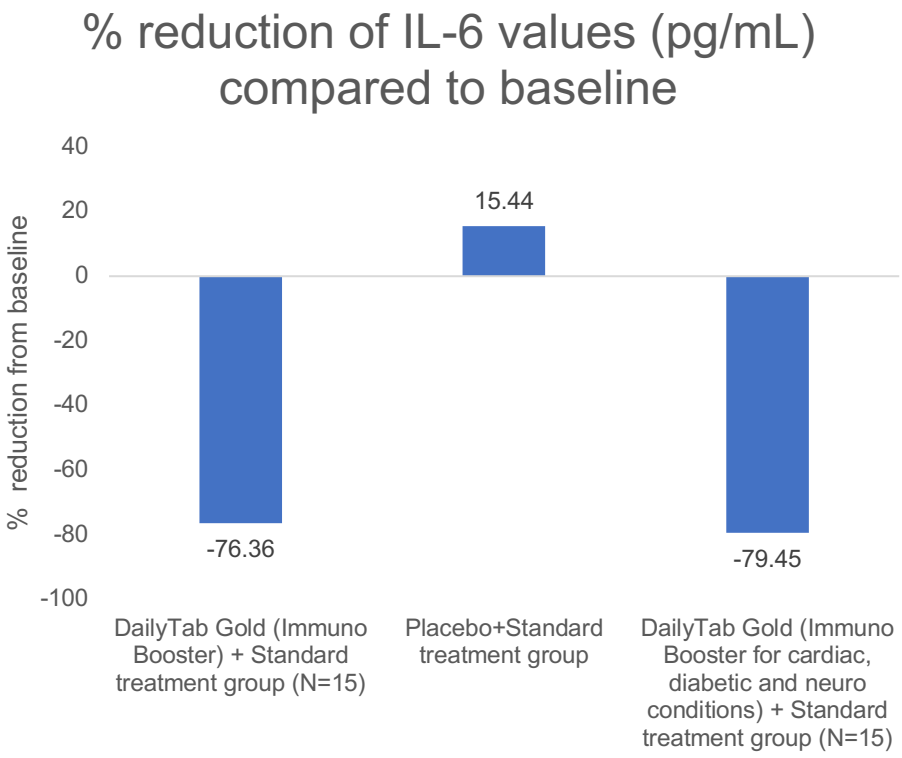


Figure 26: % change of IL-6 values (pg/mL) compared to baseline

Blood Oxygen saturation levels (SpO2)

The improvement of blood oxygen saturation levels (SpO2) were significantly different in DailyTab™ Gold (Immuno Booster) + Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment when compared to Placebo+ Standard treatment group.

The mean results of Blood oxygen saturation (SpO_2) values were 90, 93.4, 95.93 and 97.8% at baseline, Day 7, Day 14 and Day 28 in DailyTab™ Gold (Immuno Booster) + Standard treatment, respectively. The mean results of Blood oxygen saturation (SpO_2) values were 90.7, 92.79, 93.93 and 94.5% at baseline, Day 7, Day 14 and Day 28 in Placebo+ Standard treatment, respectively. The mean results of Blood oxygen saturation (SpO_2) values were 90.71, 94.13, 96.47 and 97.20% at baseline, Day 7, Day 14 and Day 28 in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment respectively.

The % improvement of blood oxygen saturation from baseline was 3.78% and 6.59% and 8.67% in DailyTab™ Gold (Immuno Booster) + Standard treatment group, 2.29%, 3.55 and 4.18 in Placebo+ Standard treatment and 3.77, 6.35 and 7.15 in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment at Day 7, Day 14 and Day 28, respectively.

Table 24: SpO_2 levels between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Variable SpO^2	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)				Placebo+ Standard treatment (N=15)				DailyTab™ Gold (Immuno Booster for cardiac, Diabetic and Neuro conditions)+ Standard treatment (N=15)			
	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28	Baseline	Day 7	Day 14	Day 28
Mean	90.00	93.40	95.93	97.80	90.71	92.79	93.93	94.50	90.71	94.13	96.47	97.20

SD	1.46	1.96	1.39	0.77	0.91	1.42	1.27	1.45	1.38	1.51	1.41	1.47
% improvement from Baseline	-	3.78	6.59	8.67		2.29	3.55	4.18	-	3.77	6.35	7.15

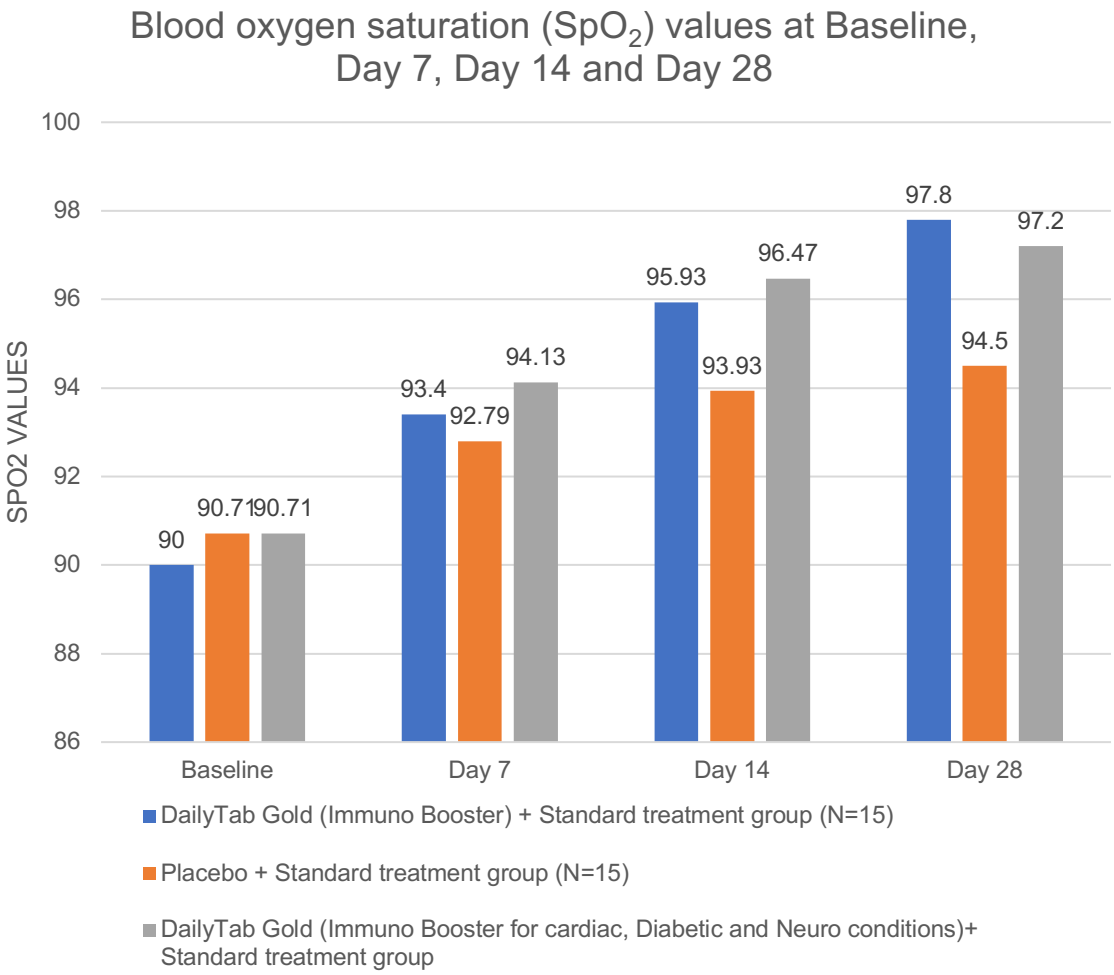


Figure 27: Blood oxygen saturation (SpO_2) values at Baseline, Day 7, Day 14 and Day 28

Table 25: % improvement of SpO_2 (%) values at Day 7, Day 14 and Day 28 between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Test	Variable	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)			Placebo+ Standard treatment (N=15)			DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment (N=15)		
		Day 7	Day 14	Day 28	Day 7	Day 14	Day 28	Day 7	Day 14	Day 28
SpO_2 (%)	Percent improvement from baseline	3.78	6.59	8.67	2.29	3.55	4.18	3.77	6.35	7.15

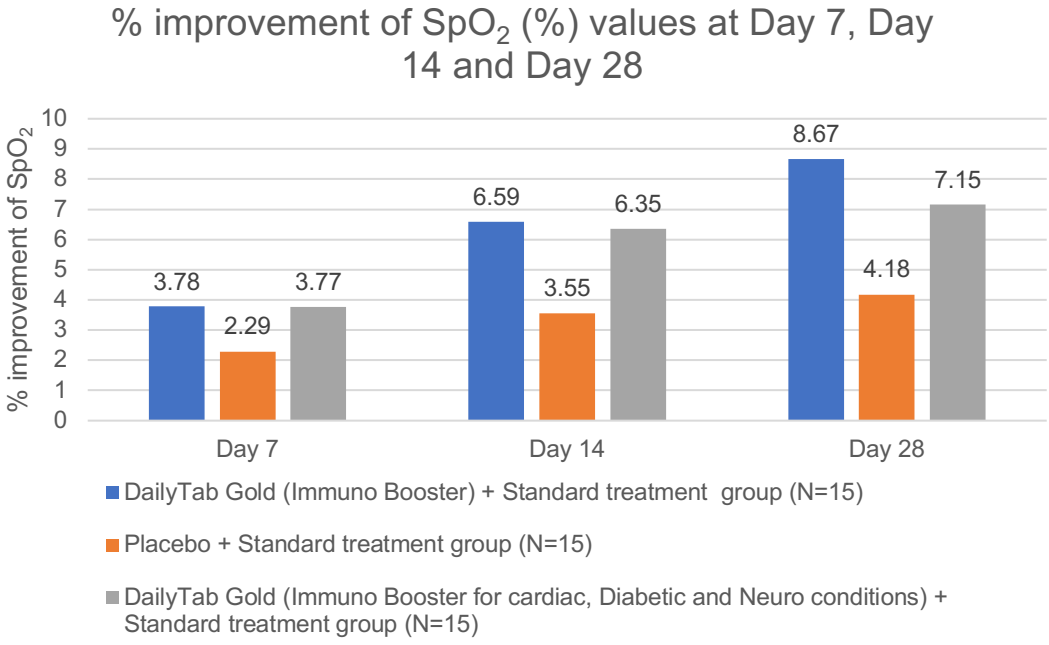


Figure 28: % improvement of SpO2 (%) values on Day 7, Day 14 and Day 28

ECG evaluation

The improvement of ECG values were significantly different in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, diabetic and neuro conditions)+Standard treatment group when compared to placebo+ standard treatment group.

The number of subjects who had normal ECG values were 7, 6 and 6 on baseline and were improved to 12, 8 and 11 in DailyTab™ Gold (Immuno Booster) +Standard treatment, Placebo +Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment respectively. The % improvement of normal ECG from baseline were 71.43%, 33.33% and 83.33% in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group, recpectively on Day 28.

Table 26: Results of ECG evaluation of DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Parameter	DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)		Placebo+ Standard treatment (N=15)		DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment (N=15)	
ECG	**Baseline**	**Day 28**	**Baseline**	**Day 28**	**Baseline**	**Day 28**
Number of subjects had normal ECG	7	12	6	8	6	11

Table 27: % of subjects with normal ECG between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Parameter	DailyTab™ Gold (Immuno Booster)+ Standard treatment group(N=15)	Placebo+ Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group (N=15)
% of subjects had normal ECG	71.43	33.33	83.33

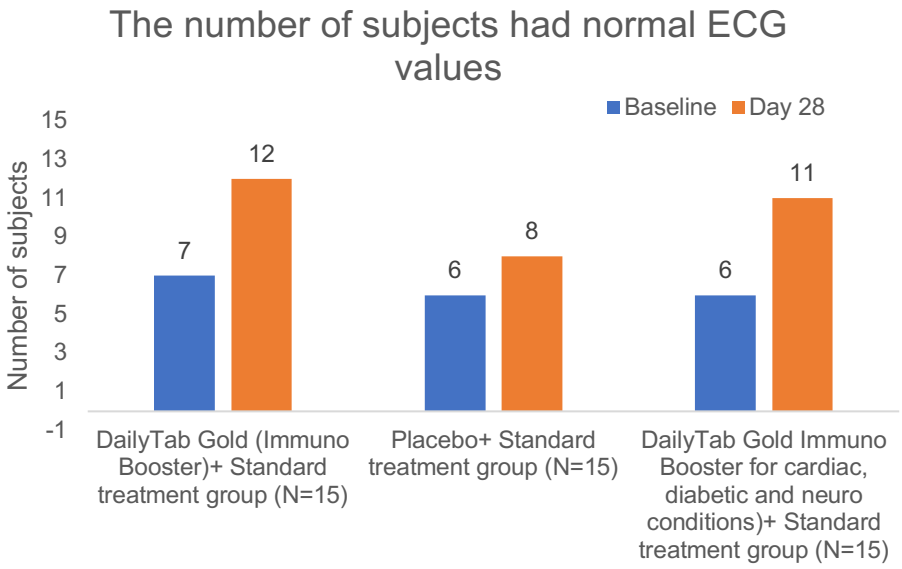


Figure 29: Number of subjects with normal ECG on baseline (day 1) and day 28

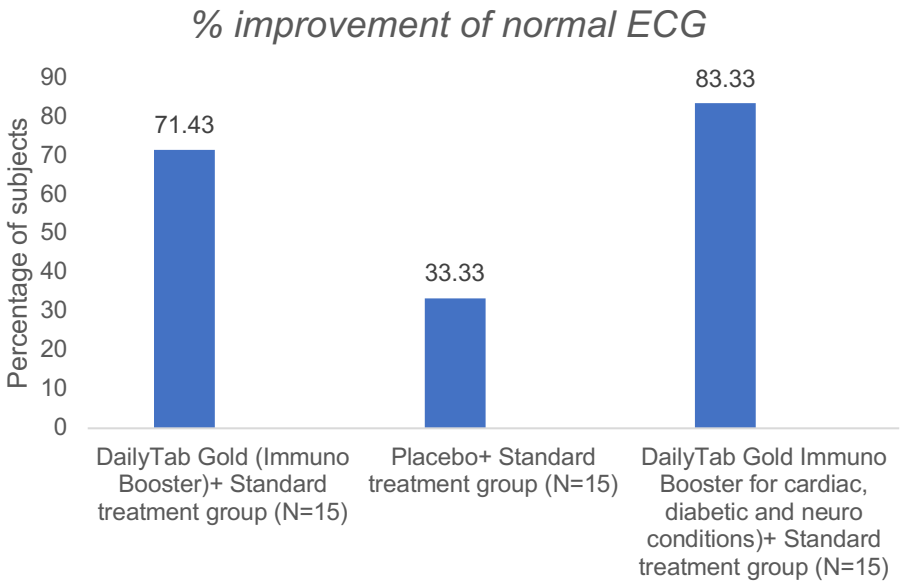


Figure 30: % change in normal ECG results on Day 28

Other subject questionnaire assessments

Medical consultation, Home care and isolation time and Bed rest time were improved in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group when compared to the placebo +Standard treatment.

Table 28: Additional procedure assessment between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Criteria for evalution		DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15)			Placebo+ Standard treatment group (N=15)			DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)		
		Day 7	Day 14	Day 28	Day 7	Day 14	Day 28	Day 7	Day 14	Day 28
Necessity of invasive assisted ventilation	No	15	15	15	15	15	15	15	15	15
	yes	0	0	0	0	0	0	0	0	0
Necessity of oxygen therapy	No	15	15	15	15	15	15	15	15	15
	yes	0	0	0	0	0	0	0	0	0
Necessity of invasive mechanical ventilation	No	15	15	15	15	15	15	15	15	15
	yes	0	0	0	0	0	0	0	0	0
Intensive care unit	No	15	15	15	15	15	15	15	15	15
	yes	0	0	0	0	0	0	0	0	0
Hospital admission	No	15	15	15	15	15	15	15	15	15
	yes	0	0	0	0	0	0	0	0	0
Medical consultation	No	13	15	15	6	9	12	13	13	15
	yes	2	0	0	9	6	3	2	2	0
Home care and isolation time	No	11	15	15	4	6	15	13	13	15
	yes	4	0	0	11	9	0	2	2	0
Bed rest time	No	11	15	15	4	4	14	13	13	15

	yes	4	0	0	11	11	1	2	2	0
Death	No	15	15	15	15	15	15	15	15	15
	yes	0	0	0	0	0	0	0	0	0

Subject perception of recovery

Subject perception scores excellent, good, Neutral, poor and very poor were 2, 13, 0, 0 and 0 in DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15), 0, 2, 0, 0, and 13 in Placebo+ Standard treatment group (N=15) and 3, 11, 0, 0 and 1 in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group.

% perception scores excellent, good, Neutral, poor and very poor were 13.3, 86.66, 0, 0 and 0 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, 0, 13.33, 0, 0 and 86.66 in Placebo+ Standard treatment group and 20, 73.33, 0, 0 and 6.66 in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, respectively.

Table 29: Subject perception of recovery between DailyTab™ Gold (Immuno Booster)+ Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group.

S. No.	Questionnaire	DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15)		Placebo+ Standard treatment group (N=15)		DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)	
		Number of subjects	% of subjects	Number of subjects	% of subjects	Number of subjects	% of subjects
1.	Excellent	2	13.3	0	0	3	20
2.	Good	13	86.6	2	13.3	11	73.33
3.	Neutral	0	0	0	0	0	0
4.	Poor	0	0	0	0	0	0

5.	Very Poor	0	0	13	86.6	1	6.66

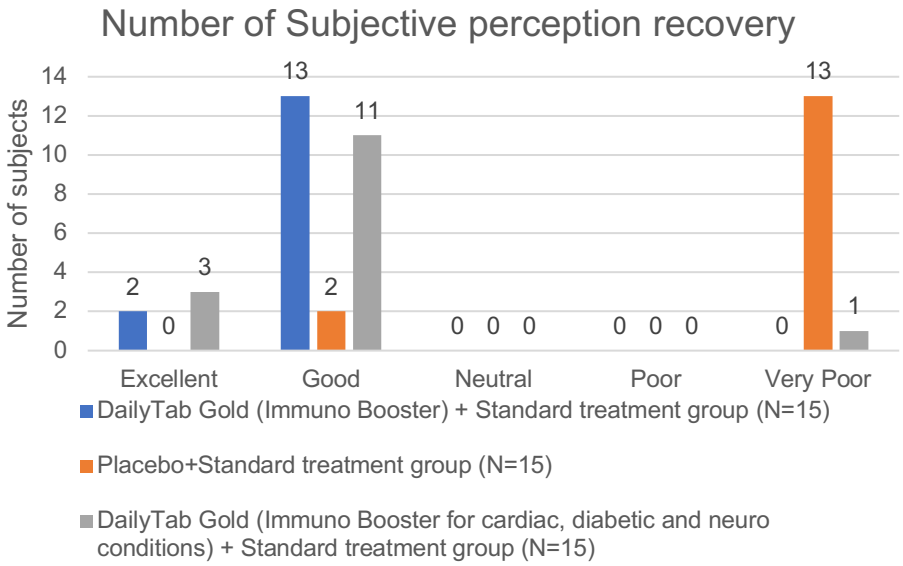


Figure 31: Recovery perception of subjects in all three groups.

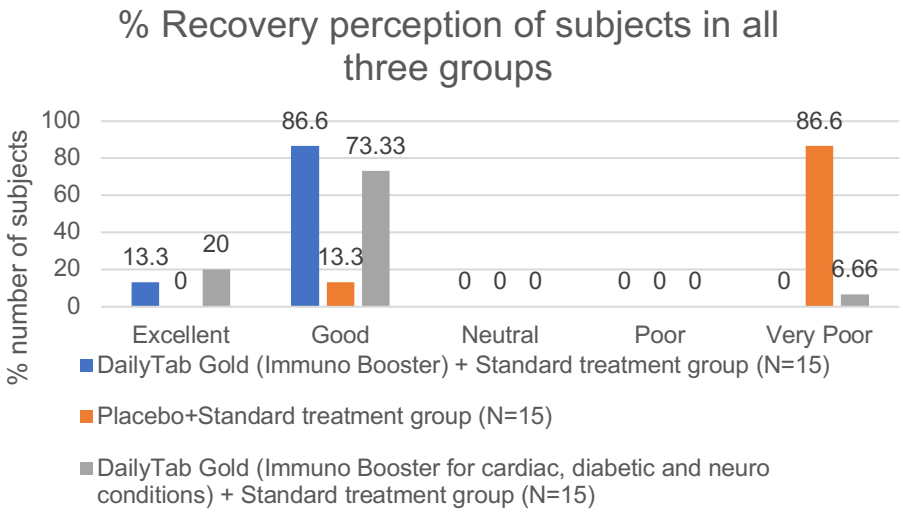


Figure 32: % Recovery perception of subjects in all three groups

23. Safety Evaluation

All patients entered into treatment who received at least one dose of the test product were included in the safety analysis.

Safety Endpoints were:

- Change in clinical laboratory findings
- Incidence of adverse events
- Change in clinical safety labs from baseline to Day 28

Extent of Exposure

S. No	DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15)	Placebo+ Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group (N=15)
Duration of exposure	28 Days	28 Days	28 Days
Dose	1 Tablet each day	1 Tablet each day	1 Tablet each day

Adverse Events

Information regarding occurrence of adverse events were captured throughout the study. Duration (start and stop dates), severity/grade, outcome, treatment and relation to study drug were recorded on the case report form (CRF).

No adverse events were noted in the study.

Table 30: Number of adverse events

S. No.	AE	DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15)	Placebo+ Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group (N=15)
1	No. of AEs	0	0	0

Deaths, Other serious adverse events and other significant adverse events

NA

Clinical laboratory evaluations

Hematological evaluation:

Mean total leukocytes counts were 4573.33, 4700 and 4646.67 cells/cumm at baseline in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group respectively. At day 28, the mean total leukocytes counts were 6750.9, 4720.77 and 6874.63 cells/cumm. The total leukocytes counts were improved in test groups when compared to placebo at Day 28.

Mean platelets counts were 2.25, 2.41 and 2.2 lakhs/cumm at baseline in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group respectively. At day 28, the mean platelets counts were 2.78, 2.21 and 3.2 lakhs/cumm. The platelet counts were improved in test groups when compared to placebo at Day 28.

Mean neutrophil counts were 57.13, 58.53 and 58.67 % at baseline in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) +

Standard treatment group respectively. At day 28, the mean neutrophils counts were 66.79, 56 and 64.11 %. The neutrophil counts were improved in test groups when compared to placebo at Day 28.

Mean lymphocyte counts were 24.2, 23 and 23 % at baseline in DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+ Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group respectively. At day 28, the mean lymphocyte counts were 31, 24 and 33.38 %. The lymphocyte counts were improved in test groups when compared to placebo+Standard treatment group at Day 28.

Mean ESR values were 17.8, 17.6 and 17.4 mm/hr at baseline in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, respectively. At day 28, the mean ESR counts were 12.36, 17.53 and 11.05 mm/hr. The ESR counts were improved in test groups when compared to placebo at Day 28.

Table 31: Comparative results of Hematology evaluation between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Lab Tests	Variable	DailyTab™ Gold (Immuno Booster)+ Standard treatment group (N=15)		Placebo+ Standard treatment group (N=15)		DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group (N=15)	
		Visit 1	Visit 4	Visit 1	Visit 4	Visit 1	Visit 4
Haemoglobin (g/dL)	Mean	13.92	13.88	13.4	13	13.75	13.68
	SD	0.56	0.75	1.04	1.19	0.89	0.88
	Min.	12.7	11.8	11.7	10.7	11.4	11.9
	Max.	14.53	14.7	14.7	14.2	15.1	14.9
Total	Mean	4573.33	6750.9	4700	4720.77	4646.67	6874.63

Leucocyte Count (Cells/cum)	SD	930.03	2298.92	1165.58	1377.81	1607.07	2184.57
	Min.	5400	4300	5100	5100	4900	4100
	Max.	8700	7200	8800	7900	9800	7300
Neutrophils (%)	Mean	57.13	66.79	58.53	56	58.67	64.11
	SD	2.07	1.93	2	8.14	3.02	11.36
	Min.	55	54	55	55	54	13.7
	Max.	62	60	64	88	65	61
Basophils (%)	Mean	0	0	0	0	0	0
	SD	0	0	0	0	0	0
	Min.	0	0	0	0	0	0
	Max.	0	0	0	0	0	0
Lymphocytes (%)	Mean	24.2	31	23	24	23	33.38
	SD	2.78	2	2.2	2.17	2.67	5.89
	Min.	28	30	27	28	27	13.7
	Max.	38	38	35	38	35	38
Eosinophils (%)	Mean	3.67	3.36	3.6	3.4	3.4	4.11
	SD	0.72	0.74	0.51	0.51	0.83	2.7
	Min.	3	2	3	3	2	3
	Max.	5	5	4	4	5	13.7
Monocytes (%)	Mean	4.8	4.86	4.87	4.6	4.93	5.38
	SD	1.01	1.03	0.92	0.99	1.28	2.51
	Min.	3	3	3	3	3	3
	Max.	6	6	6	6	7	13.7
RBC (million/cumm)	Mean	4.65	4.64	4.53	4.1	4.6	5.17
	SD	0.19	0.25	0.36	0.41	0.29	2.38
	Min.	4.23	3.93	3.9	3.56	3.8	3.96
	Max.	4.83	4.92	4.9	4.73	5.03	13.7
Platelets Lakhs/cumm	Mean	2.25	2.78	2.41	2.21	2.2	3.2
	SD	0.4	0.32	0.38	0.28	0.43	0.6
	Min.	2.17	1.98	2.02	1.90	1.59	2.04
	Max.	3.45	3.01	3.12	3.1	3.18	3.98
MCH (fL)	Mean	83.73	83.29	82.13	81.4	82.67	78.45
	SD	3.99	2.61	3	2.69	3.85	18.1
	Min.	79	77	79	76	77	13.7

	Max.	92	87	87	85	95	88
ESR (mm/hr)	Mean	17.8	12.36	17.6	17.53	17.4	11.05
	SD	1.7	0.84	2.23	2.23	2.72	4.78
	Min.	12	11	11	10	11	12
	Max.	18	14	19	19	22	31.1

Biochemical evalaution

There were no significant biochemical tests differences in values of RBS, Sodium, Potassium, Bilirubin, BUN, AST, ALT, ALP, creatinine, and albumin between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group, respectively.

Table 32: Comparative biochemical assessments between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group.

		DailyTab™ Gold (Immuno Booster)+ Standard treatment group (N=15)		**Placebo+ Standard treatment group (N=15)**		**DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)**	
		Day 1	**Day 28**	**Day 1**	**Day 28**	**Day 1**	**Day 28**
RBS (mg/dL)	Mean	97.80	98.14	98.44	99.88	115.27	94.02
	SD	16.75	26.36	25.89	18.61	45.05	46.18
	Min.	79	79	73.3	72.3	74	1.6
	Max.	146	166	142	136	234	206
Sodium	Mean	138.71	129.97	138.00	138.23	137.63	131.05

(mmol/L)	SD	1.93	36.27	2.63	2.51	2.17	32.51
	Min.	133.2	4.2	135.2	135	133.1	13.7
	Max.	141	143.1	143	144	141	143
Potassium (mmol/L)	Mean	6.64	3.91	9.04	4.18	4.10	4.75
	SD	9.51	0.77	12.57	0.28	0.15	2.48
	Min.	4	1.4	3.9	3.8	3.8	3.8
	Max.	41	4.8	40	4.8	4.3	13.7
Total Bilurubin (mg/dL)	Mean	1.33	1.45	1.39	1.33	1.33	1.26
	SD	0.14	0.22	0.12	0.17	0.13	0.07
	Min.	1.1	1.2	1.2	1.2	1.1	1.2
	Max.	1.6	32	1.5	1.8	1.5	1.4
Blood Urea (mg/dL)	Mean	24.20	33.46	23.36	35.61	25.27	38.10
	SD	5.56	17.36	6.25	24.77	4.27	25.40
	Min.	12	21	13	12	19	21
	Max.	34	75.2	34	81.2	33	97
AST (U/L)	Mean	29.20	24.00	29.07	28.43	28.67	25.71
	SD	3.86	3.21	3.53	4.94	5.43	2.27
	Min.	21	22	24	21	22	21
	Max.	37	33	38	37	44	29
ALT (U/L)	Mean	37.47	31.93	35.73	32.71	33.28	30.79
	SD	9.26	4.20	7.30	5.11	11.81	3.45
	Min.	24	26	28	24	0.2	24
	Max.	59	41	57	42	59	38
ALP (U/L)	Mean	72.65	66.91	72.19	61.51	72.27	70.04
	SD	12.13	26.58	14.23	16.85	18.73	23.98
	Min.	58.2	1.1	44.2	28	35	3.2
	Max.	98.2	95	99.5	83.1	122.1	92.2
Creatinine (mg/dL)	Mean	1.05	1.08	1.05	1.01	1.02	0.92
	SD	0.11	0.50	0.08	0.07	0.11	0.07
	Min.	0.8	0.8	0.9	0.9	0.8	0.8
	Max.	1.2	2.8	1.2	1.2	1.2	1
Albumin	Mean	3.91	3.68	4.17	5.35	4.24	4.86

(g/dL)	SD	0.31	1.01	0.38	4.00	0.57	2.98
	Min.	3.5	0.56	3.4	3.3	3.4	3.4
	Max.	4.8	5.3	4.8	18.18	5.2	15.11

Urinalysis

Table 33: Urine analysis results

	Test	**DailyTab™ Gold (Immuno Booster) + Standard treatment (N=15)**		**Placebo+ Standard treatment (N=15)**		**DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment (N=15)**	
		Day 1	Day 28	Day 1	Day 28	Day 1	Day 28
Colour	Pale yellow	15	15	15	15	15	15
Appearance	Clear	15	15	15	15	15	15
Specific gravity	Mean	1.02	1.02	1.02	1.02	1.02	1.02
	SD	0.00	0.00	0.00	0.00	0.00	0.00
	Min	1.02	1.02	1.01	1.01	1.01	1.02
	Max	1.03	1.03	1.02	1.02	1.03	1.03
PH	Mean	6.89	6.91	6.88	6.91	6.91	6.89
	SD	0.15	0.08	0.15	0.05	0.15	0.07
	Min	6.50	6.70	6.50	6.80	6.50	6.70
	Max	7.00	7.00	7.10	7.00	7.10	7.00
Protein	Absent	15	15	15	15	15	15
Sugar	Absent	15	15	15	15	15	15

Ketone	Absent	15	15	15	15	15	15
Nitrate	Negative	15	15	15	15	15	15
RBC/HPF	Nil	15	15	15	15	15	15
Epithelial cells	1-2	13	15	14	15	13	14
	1-3	1	0	0	0	0	1
	2-4	1	0	1	0	2	0
Casts & crystals	Nill	15	15	15	15	15	15
Bile salts	Negative	15	15	15	15	15	15
Bile Pigment	Negative	15	15	15	15	15	15
Urobilinogen	Normal	15	15	15	15	15	15
	Abnormal	0	0	0	0	0	0

Vital Signs, Physical findings, and Other Observations Related to Safety

Visit: 2 Day 7 vital examination:
Table 34: Vital signs evaluation

S. No	Vital signs	Variable	DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment group (N=15)	Placebo + Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)

1.	**Systolic BP (mmhg)**	**Mean**	124.80	127.17	117.87
		SD	7.40	4.13	29.84
		Min	118.00	122.00	12.00
		Max	148.00	138.00	140.00
2.	Diastolic BP (mmhg)	**Mean**	83.73	83.83	83.07
		SD	4.65	1.03	3.61
		Min	78.00	82.00	78.00
		Max	98.00	86.00	90.00
3.	Pulse Rate /bpm	**Mean**	83.47	83.00	84.93
		SD	9.43	6.95	10.11
		Min	76.00	76.00	68.00
		Max	102.00	98.00	108.00
4.	Respiratory Rate /min	**Mean**	19.67	18.42	19.00
		SD	2.16	1.24	1.96
		Min	18.00	17.00	17.00
		Max	24.00	21.00	24.00
5.	Body Temperature	**Mean**	98.61	99.20	98.45
		SD	0.53	1.16	0.38
		Min	98.20	98.30	98.20
		Max	99.80	102.50	99.80
		SD	98.61	99.20	98.45

Visit: 3 (Day 14)

S. No	**Vital signs**	**Variable**	**DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment group (N=15)**	**Placebo + Standard treatment group (N=15)**	**DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)**

1.	Systolic BP (mmhg)	**Mean**	128.67	126.64	126.27
		SD	7.39	5.17	5.80
		Min	120.00	120.00	120.00
		Max	140.00	140.00	140.00
2.	Diastolic BP (mmhg)	**Mean**	83.07	84.21	83.67
		SD	3.20	2.72	3.06
		Min	80.00	79.00	78.00
		Max	90.00	90.00	88.00
3.	Pulse Rate /bpm	**Mean**	84.27	83.36	84.40
		SD	5.12	5.23	6.29
		Min	78.00	76.00	76.00
		Max	98.00	92.00	98.00
4.	Respiratory Rate /min	**Mean**	18.27	18.50	18.33
		SD	0.59	0.85	0.49
		Min	17.00	17.00	18.00
		Max	19.00	20.00	19.00
5.	Body Temperature	**Mean**	98.29	98.34	98.35
		SD	0.08	0.07	0.09
		Min	98.20	98.20	98.20
		Max	98.50	98.40	98.50
		SD	98.29	98.34	98.35

Visit: 4 (Day 28)

S. No	**Vital signs**	**Variable**	**DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment group (N=15)**	**Placebo + Standard treatment group (N=15)**	**DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group**

					(N=15)
1.	Systolic BP (mmhg)	**Mean**	125.20	123.64	122.93
		SD	6.54	5.37	5.01
		Min	110.00	110.00	110.00
		Max	140.00	130.00	130.00
2.	Diastolic BP (mmhg)	**Mean**	82.27	80.86	81.87
		SD	3.01	4.82	3.25
		Min	78.00	70.00	78.00
		Max	90.00	90.00	90.00
3.	Pulse Rate /bpm	**Mean**	81.60	82.86	83.07
		SD	4.61	3.90	5.55
		Min	76.00	74.00	76.00
		Max	92.00	88.00	96.00
4.	Respiratory Rate /min	**Mean**	18.20	18.21	18.13
		SD	0.68	0.58	0.83
		Min	17.00	17.00	17.00
		Max	19.00	19.00	19.00
5.	Body Temperature	**Mean**	98.29	98.39	98.41
		SD	0.56	0.11	0.12
		Min	96.30	98.20	98.10
		Max	98.60	98.60	98.60
		SD	98.29	98.39	98.41

24. Post follow up at Day 35

Table 35: Post follow up findings at Day 35

Variables	Variable	DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment group (N=15)	Placebo + Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)
Subject's health status	Normal	15	15	15
	Abnormal	0	0	0
Adverse events	Yes	0	0	0
	No	15	15	15
Did the AE resulted in death	yes	0	0	0
	No	15	15	15
Worsening sign/symptoms/ Or showing no improvement after end of study	Yes	0	3	0
	No	15	12	15
Protocol violations	Yes	0	0	0
	No	15	15	15
Patient withdrew informed consent	Yes	0	0	0
	No	15	15	15
Patient lost to follow up	Yes	0	0	0
	No	15	15	15

25. Subject's Global assessment of symptoms at Day 35

Table 36: Subject's Global assessment of symptoms at Day 35

Symptoms	Variables	DailyTab™ Gold (Immuno Booster) + Standard treatment + Standard treatment group (N=15)	Placebo + Standard treatment group (N=15)	DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group (N=15)
Cough	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Fever with or without chill	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Difficulty in breathing	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Body pain	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Nasal congestion	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Gastroin	Nil	15	15	15

testinal sympto ms	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Fatigue	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0
Headach e	Nil	15	15	15
	Mild	0	0	0
	Moderate	0	0	0
	Severe	0	0	0

26. Discussion and Conclusion

Out of 54 patients screened, 9 were found screen failures. 5 subjects of screen failures were severe covid-19 subjects, 2 subjects were ICF withdrawn and 2 subjects were need of ICU. 45 patients underwent randomization, of these patients were assigned to receive DailyTab™ Gold (Immuno Booster) + Standard treatment, 15 patients were assigned to receive Placebo+ Standard treatment group and 15 patients assigned to DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment as per randomization chart.

The mean age of the subjects was 37, 38.14 and 39.47 years in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

The mean height of the subjects were 166.07, 163.86 and 164.60 cm in DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+Standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment respectively. The average BMI of the subjects were 27.08, 27.54 and 27.29 kg/m^2 in DailyTab™ Gold (Immuno Booster) + Standard treatment, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment respectively.

There were no important differences in other demographic characteristics between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group. Data from all 45 subjects who completed the study were analyzed.

There were no significant differences between the vital signs blood pressure, body temperature, respiratory rate and body temperature between the groups at baseline. There were no significant differences on preexisting conditions, baseline symptoms and prior and concomitant medications between the groups.

In DailyTab™ Gold (Immuno Booster) + Standard treatment group, pre-existing medical conditions were hysterectomy, diabetes mellitus and hypertension. In Placebo + Standard

treatment group, pre-existing medical conditions were hypothyroidism, diabetes mellitus and hypertension. In DailyTab™ Gold (Immuno Booster for cardiac, diabetic and neuro conditions) + Standard treatment group, pre-existing medical conditions were hypothyroidism, and hypertension. All 45 subjects were treatment compliant.

There were no significant difference between baseline symptoms and standard treatments given between DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+standard treatment and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment groups.

Efficacy results:

Clinical status on 7 point ordinal scale,:

In DailyTab™ Gold (Immuno Booster) + Standard treatment group, 13 out of 15 subjects were found with no clinical or virological evidence of infection after treatment for 28 days. Remaining 1 subject was found not hospitalized and had no limitation of activities. In Placebo + Standard treatment group, 3 out of 15 subjects were found with no clinical or virological evidence of infection after treatment for 28 days. Other 7 subject were found not hospitalized and had no limitation of activities and remaining 5 subjects were found not hospitalized and had limitation of activities. In DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, 14 subjects out of 15 subjects were found with no clinical or virological evidence of infection after treatment for 28 days. The odd ratio was found statistically significant when compared to placebo in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment groups.

RT PCR test results:

On day 14 post-inclusion, 14 out of 15 patients of DailyTab™ Gold (Immuno Booster) +Standard treatment treated patients were virologically cured compared to 8 out of 15 patients in the placebo+Standard treatment group (p= 0.001). Where as 15 out of 15 patients of DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group were found to be virologically cured comparatively.

Subject global assessment:

The disappearance rates of major symptoms were high in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to the baseline and also when compared with Placebo+standard treatment.

Subject symptom assessment (Diary card reconciliation):

The mean scores of symptoms (Nil-0, Mild- 1, Moderate-2 and Severe- 3) were assessed from Day 1 to Day 28 by subject questionnaire and showed improvement in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared with day 1 scores and also when compared with Placebo +Standard treatment group.

Improvement in Chest X-ray:

Chest X-ray was performed at baseline and after 28 days of treatment. 13 out of 15 subjects had improved chest X-ray results in DailyTab™ Gold (Immuno Booster) + Standard treatment group, 14 out of 15 subjects had improved the chest X-ray results in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group. 86.67% and 93.33 % of patients were improved the pulmonary results in chest X-ray of DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to 46.67% of patients treated with Placebo + standard treatment group.

Changes in Hs-CRP vaues (mg/L):

The change rate of Hs-C reactive protein was favourable for DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to placebo + standard treatment alone. The mean results of Hs-CRP values at baseline were 103.95, 88.04 and 78.06 mg/L in DailyTab™ Gold (Immuno Booster) + Standard treatment group, placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group respectively. After 28 days of treatment the CRP changed values were 3.35, 75.14 and 15.6 mg/L, respectively. The change in values were statistically significant when compared to Placebo on Day 28.

Changes in IL-6 values (pg/mL):

The change of IL-6 values were significantly different in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group when compared to Placebo+standard treatment group. At baseline, the mean values of IL-6 values were 20.6 pg/mL, 19.17 pg/mL and 20.49 pg/mL in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, respectively. After treatment for 28 days, the values were 4.87 pg/mL, 22.13 pg/mL and 4.21 pg/mL, respectively. The % change of IL-6 was -76.36, 15.44 and -79.45 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group, respectively. The results were statistically significant.

Changes in Blood oxygen saturation levels (SpO2):

The improvement of blood oxygen saturation levels (SpO2) were significantly different in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group when compared to Placebo+ standard treatment group. The mean results of blood oxygen saturation (SpO_2) values were 90, 93.4, 95.93 and 97.8% at baseline, Day 7, Day 14 and Day 28 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, respectively. The mean results of Blood oxygen saturation (SpO_2) values were 90.7, 92.79, 93.93 and 94.5% at baseline, Day 7, Day 14 and Day 28 in Placebo+ Standard treatment, respectively. The mean results of Blood oxygen saturation (SpO_2) values were 90.71, 94.13, 96.47 and 97.20% at baseline, Day 7, Day 14 and Day 28 in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group, respectively.The % improvement of blood oxygen saturation from baseline was 3.78% and 6.59% and 8.67% in DailyTab™ Gold (Immuno Booster) + Standard treatment group, 2.29%, 3.55% and 4.18% in Placebo+ Standard treatment and 3.77%, 6.35% and 7.15% in

DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) Standard treatment group on Day 7, Day 14 and Day 28, respectively.

ECG results:

The number of subjects having normal ECG values were 7, 6 and 6 at baseline which improved to 12, 8 and 11 subjects in DailyTab™ Gold (Immuno Booster) +Standard treatment group, Placebo +Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group, respectively. The % improvement of normal ECG from baseline were 71.43%, 33.33% and 83.33% in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+Standard treatment group, respectively on Day 28.

Other assessments:

Medical Consultation, Home care and isolation time and Bed rest time were improved in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group when compared to the placebo+ Standard treatment group.

Subject perception of recovery:

The number of subjects with subject perception scores excellent, good, Neutral, poor and very poor were 2, 13, 0, 0 and 0 in DailyTab™ Gold (Immuno Booster) + Standard treatment group (N=15), 0 , 2, 0, 0, and 13 in Placebo+ Standard treatment group (N=15) and 3, 11, 0, 0 and 1 in DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group.

Safety evaluation:

There were no adverse events reported. No serious adverse events and deaths were reported. There were no significant hematological & biochemical tests differences in values between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group, respectively. Urine analysis results were found normal in between DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac,

Diabetic and Neuro conditions)+ Standard treatment group. Urine pregnancy test were negative for female patients of child bearing potential. All female subjects showed negative urine pregnancy test in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) + Standard treatment group. All the vital signs were found with in the normal range on day 28. The subjects maintained healthy normal at follow up visit on Day 21 in DailyTab™ Gold (Immuno Booster) + Standard treatment group, Placebo+ Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group. There were no worsening of clinical symptoms after treatment in any of the three groups. There were no protocol violations and deviations reported.

Overall conclusion:

Clinical status was improved in DailyTab™ Gold (Immuno Booster) + Standard treatment group and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions)+ Standard treatment group when compared to Placebo+ Standard treatment group.

DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with standard treatment were very effective in virological cure for COVID 19 group.

The DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with standard treatment reduced the COVID 19 symptoms when compared to the baseline and also when compared to the Placebo+standard treatment group.

The DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with standard treatment reduced the Inflammatory marker CRP and cytokine IL-6 levels when compared to the baseline and also when compared to the placebo + standard treatment group.

The DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with standard treatment improved the Blood oxygen saturation levels when compared to the Placebo+Standard treatment.

The DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) improved the normal Chest X-Ray.

There were no adverse events or serious adverse events reported.

All the biochemical tests were found normal at baseline and post study.

Overall DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) along with standard treatment were very effective in the treatment of the COVID-19 disease. The DailyTab™ Gold (Immuno Booster) and DailyTab™ Gold (Immuno Booster For cardiac, Diabetic and Neuro conditions) were tolerated very well.

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28. Appendices

S. No.	Appendices	Document
1.	Study information	Study Protocol
		Sample CRF
		Informed Consent
		Ethics approval letter
		Randomization sheet
		CTRI registration copy
		Important publication referenced in the report
2.	Patient data listings	Demographic data
		Individual efficacy response data
		Adverse events listing (each patient)
		Individual laboratory measurements (each patient)
3.	Case record forms	CRFs
4.	Others	Individual patient data listings