

Name of Study : Immune booster Camphora 1000 c in reducing Covid-19

Protocol Number : PROTOCOL NO- MHC/CT/20-21/019

Site Name : Site 20 (PROTOCOL NO- MHC/CT/20-21/019)

Patient ID : 0020

Basic Details

Research Site : Site 20 (PROTOCOL NO- MHC/CT/20-21/019)

Subject's Screening I.D : 0020

Subject's Initial : ARG

Age (Yrs.) : 25

Sex : Male

Telephone no : 7350319299

Mobile No : 7350319299

Email : -

Occupation : -

Monthly Income : -

Address : N-6 Cidco Aurangabad

Screening

History of previous illness : NO

Family History

Any Known H/o hypersensitivity? : No

Has the patient entered into the study phase? : Yes

WRITTEN INFORMED CONSENT TAKEN? : Yes

Presenting Complaint with duration : NO

CHECK LIST FOR INCLUSION CRITERIA

- 1) Asymptomatic (w.r.t Covid-19 illness) subjects with community exposure from household or workplaces or high risk frontline workers etc : Yes
- 2) Age > 20 yrs Yes
- 3) Written Informed consent : Yes
- 4) Individuals not detected with COVID 19 antibodies (Both IgG and IgM) at screening and negative with RT-PCR test as well : Yes
- 5) All existing co morbidities with stable prescription : Yes

CHECK LIST FOR EXCLUSION CRITERIA

- 1) All COVID-19 positive RT- PCR cases (Symptomatic and asymptomatic). : No
 - 2) Individuals detected with any of the COVID 19 antibodies ie any of IgG and IgM at the time of screening : No
 - 3) COVID 19 cases with mild to moderate symptoms e.g. Fever, Cough-Dry or productive, Throat Pain, Nasal congestion, Coryza, Myalgia, Weakness, Headache, diarrhoea. : No
 - 4) Women who are Pregnant or Lactating : No
 - 5) Age group below 20 years. : No
 - 6) Patients with pre-existing conditions: ESRD, HIV, Cancer of any organ or system on active chemo therapy or radiation. Cancer Survivor. : No
 - 7) Known Immune suppressed health status due use of oral steroids, immune-modulators as treatment for chronic co morbidities : No
 - 8) Known cases of acute exacerbation of: IHD, COPD, Asthma. : No
 - 9) Those with end stage renal disease and progressive liver dysfunctions : No
 - 10) Anyone who has taken HCQS in previous one week or Homoeopathic prophylaxis Ars alb 30 in last 15 days or must not have used any other similar medicines for boosting the immunity against Covid-19 illness. : No
- Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (⁰ F) : 96.9
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

PRE-EXISTING MEDICAL CONDITION

- 1) Chronic Lung Disease (asthma/emphysema/COPD) : NO
- 2) Diabetes Mellitus : NO
- 3) Cardiovascular disease : NO
- 4) Chronic Renal disease : NO
- 5) Chronic Liver disease : NO
- 6) Immunocompromised Condition : NO
- 7) Neurologic/neurodevelopmental : NO
- 8) Other chronic diseases : NO
- 9) Pregnant female : NO
- 10) Current smoker : NO
- 11) Any other : NO

PAST MEDICAL HISTORY:

- 1) Disease details with duration : NO
- 2) Age : NO
- 3) Medication taken : NO
- 4) Recovered=1; Not recovered=2 : NO

Handed over the investigational product:

- 1) YES : YES
- 2) NO : -

PERSONAL HISTORY:

- 1) Born and brought up- : Nehgudi
- 2) Education- : B.E Mech
- 3) Diet- Veg/Non veg : Non-veg
- 4) Addictions : NO
- 5) Smoking Y/N : NO
- 6) If Yes, how many cigarettes per day : -
- 7) If left smoking, how many years ago : -
- 8) Any additional information : WT- 51.9 KG

SYSTEMIC EXAMINATION:

- 1) Respiratory system : NAD
- 2) Cardiovascular system- : NAD

- 3) Nervous system : NAD
- 4) Gastro-intestinal system : NAD
- 5) Genito urinary system- : NAD
- 6) Loco motor system : NAD

Results of COVID 19 antibody Tests

- 1) visit date : 9/11/20
- 2) Test result : 0.94
- 3) Inference : Negative

Assessment incidence of Covid 19

- 1) Date : 9/11/20
- 2) RT-PCR-COVID 19 : Negative

Assessment of symptoms

- 1) Fever : 1
- 2) Myalgia : 1
- 3) Malaise : 1
- 4) Arthralgia : 1
- 5) Headache : 1
- 6) Confusion : 1
- 7) Diarrhea : 1
- 8) Vomiting : 1
- 9) Dry cough : 1
- 10) Sputum : 1
- 11) Coryza : 1
- 12) Throat pain : 1
- 13) Dyspnoea : 1
- 14) Chest pain : 1
- 15) SPO2 : 98%
- 16) BP : 129/85
- 17) Clinical status : 6

HOSPITALIZATION DETAILS: (If required)

- 1) Symptoms at hospitalization : NA
- 2) Date of admission : NA
- 3) Date of discharge : NA

COMPLIANCE DETAILS

- 1) Compliant : YES
- 2) Noncompliant : -

Visit day 0

Visit 1

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA

Temperature (⁰ F) : 99.1
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

Assessment of symptoms

- 1) Fever : 1
- 2) Myalgia : 1
- 3) Malaise : 1
- 4) Arthralgia : 1
- 5) Headache : 1
- 6) Confusion : 1
- 7) Diarrhea : 1
- 8) Vomiting : 1
- 9) Dry cough : 1
- 10) Sputum : 1
- 11) Coryza : 1
- 12) Throat pain : 1
- 13) Dyspnoea : 1
- 14) Chest pain : 1
- 15) SPO2 : 98%
- 16) BP : 120/80
- 17) Clinical status : 6

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

- 1) Rescue Medication : NA
- 2) Dose : NA
- 3) Frequency : NA
- 4) Start Date : NA
- 5) Stop Date : NA

Subject Score : NA
Subject Diary Card Given : No

Visit 2

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (⁰ F) : NA
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

Assessment of symptoms

- 1) Fever : 1
- 2) Myalgia : 1
- 3) Malaise : 1
- 4) Arthralgia : 1
- 5) Headache : 1
- 6) Confusion : 1
- 7) Diarrhea : 1
- 8) Vomiting : 1
- 9) Dry cough : 1
- 10) Sputum : 1
- 11) Coryza : 1
- 12) Throat pain : 1
- 13) Dyspnoea : 1
- 14) Chest pain : 1
- 15) SPO2 : NA
- 16) BP : NA
- 17) Clinical status : 6

COMPLIANCE DETAILS

- 1) Compliant : YES
- 2) Noncompliant : -

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

- 1) Rescue Medication : NA
- 2) Dose : NA
- 3) Frequency : NA
- 4) Start Date : NA
- 5) Stop Date : NA

REVIEW OF ADVERSE EVENTS & CONCOMITANT MEDICATION:

- 1) Did the subject experience any adverse event : NO
- 2) Did the subject take any concomitant medications : NO

Visit 3

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (° F) : 98

Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD

Respiratory : NAD

GIT : NAD

CNS : NAD

Questionnaire

Assessment incidence of Covid 19

1) Date : NO

2) RT-PCR-COVID 19 : NO

Assessment of symptoms

1) Fever : 1

2) Myalgia : 1

3) Malaise : 1

4) Arthralgia : 1

5) Headache : 1

6) Confusion : 1

7) Diarrhea : 1

8) Vomiting : 1

9) Dry cough : 1

10) Sputum : 1

11) Coryza : 1

12) Throat pain : 1

13) Dyspnoea : 1

14) Chest pain : 1

15) SPO2 : 98%

16) BP : 120/75

17) Clinical status : 6

COMPLIANCE DETAILS

1) Compliant : YES

2) Noncompliant : -

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

1) Rescue Medication : NA

2) Dose : NA

3) Frequency : NA

4) Start Date : NA

5) Stop Date : NA

REVIEW OF ADVERSE EVENTS & CONCOMITANT MEDICATION:

1) Did the subject experience any adverse event : NO

2) Did the subject take any concomitant medications : NO

Visit 4

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (⁰ F) : NA
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

Assessment of symptoms

- 1) Fever : 1
- 2) Myalgia : 1
- 3) Malaise : 1
- 4) Arthralgia : 1
- 5) Headache : 1
- 6) Confusion : 1
- 7) Diarrhea : 1
- 8) Vomiting : 1
- 9) Dry cough : 1
- 10) Sputum : 1
- 11) Coryza : 1
- 12) Throat pain : 1
- 13) Dyspnoea : 1
- 14) Chest pain : 1
- 15) SPO2 : NA
- 16) BP : NA
- 17) Clinical status : 6

COMPLIANCE DETAILS

- 1) Compliant : YES
- 2) Noncompliant : -

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

- 1) Rescue Medication : NA
- 2) Dose : NA
- 3) Frequency : NA
- 4) Start Date : NA
- 5) Stop Date : NA

REVIEW OF ADVERSE EVENTS & CONCOMITANT MEDICATION:

- 1) Did the subject experience any adverse event : NO
- 2) Did the subject take any concomitant medications : NO

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (⁰ F) : NA
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

Assessment incidence of Covid 19

- 1) Date : NO
- 2) RT-PCR-COVID 19 : NO

Assessment of symptoms

- 1) Fever : 1
- 2) Myalgia : 1
- 3) Malaise : 1
- 4) Arthralgia : 1
- 5) Headache : 1
- 6) Confusion : 1
- 7) Diarrhea : 1
- 8) Vomiting : 1
- 9) Dry cough : 1
- 10) Sputum : 1
- 11) Coryza : 1
- 12) Throat pain : 1
- 13) Dyspnoea : 1
- 14) Chest pain : 1
- 15) SPO2 : NA
- 16) BP : NA
- 17) Clinical status : 6

COMPLIANCE DETAILS

- 1) Compliant : YES
- 2) Noncompliant : -

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

- 1) Rescue Medication : NA
- 2) Dose : NA
- 3) Frequency : NA
- 4) Start Date : NA
- 5) Stop Date : NA

REVIEW OF ADVERSE EVENTS & CONCOMITANT MEDICATION:

- 1) Did the subject experience any adverse event : NO
- 2) Did the subject take any concomitant medications : NO

Visit 6

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (⁰ F) : NA
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

Assessment of symptoms

- 1) Fever : 1
- 2) Myalgia : 1
- 3) Malaise : 1
- 4) Arthralgia : 1
- 5) Headache : 1
- 6) Confusion : 1
- 7) Diarrhea : 1
- 8) Vomiting : 1
- 9) Dry cough : 1
- 10) Sputum : 1
- 11) Coryza : 1
- 12) Throat pain : 1
- 13) Dyspnoea : 1
- 14) Chest pain : 1
- 15) SPO2 : NA
- 16) BP : NA
- 17) Clinical status : 6

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

- 1) Rescue Medication : NA
- 2) Dose : NA
- 3) Frequency : NA
- 4) Start Date : NA
- 5) Stop Date : NA

REVIEW OF ADVERSE EVENTS & CONCOMITANT MEDICATION:

- 1) Did the subject experience any adverse event : NO

2) Did the subject take any concomitant medications : NO

Visit 7

Concomitant Illnesses and Medication (If Any) : NO

GENERAL EXAMINATION

Pulse (per min) : NA
Temperature (⁰ F) : 97.1
Respiratory Rate (per min) : NA

Systemic Examination-Please record if any abnormality is noted

CVS : NAD
Respiratory : NAD
GIT : NAD
CNS : NAD

Questionnaire

Results of COVID 19 antibody Tests

1) visit date : 6/1/2021
2) Test result : 0.083
3) Inference : Negative

Assessment incidence of Covid 19

1) Date : NO
2) RT-PCR-COVID 19 : NO

Assessment of symptoms

1) Fever : 1
2) Myalgia : 1
3) Malaise : 1
4) Arthralgia : 1
5) Headache : 1
6) Confusion : 1
7) Diarrhea : 1
8) Vomiting : 1
9) Dry cough : 1
10) Sputum : 1
11) Coryza : 1
12) Throat pain : 1
13) Dyspnoea : 1
14) Chest pain : 1
15) SPO2 : 98%
16) BP : 141/68
17) Clinical status : 6

RESCUE MEDICATION(S) FOR NON HOSPITALIZED SUBJECTS:

1) Rescue Medication : NA
2) Dose : NA

- 3) Frequency : NA
- 4) Start Date : NA
- 5) Stop Date : NA

REVIEW OF ADVERSE EVENTS & CONCOMITANT MEDICATION:

- 1) Did the subject experience any adverse event : NO
- 2) Did the subject take any concomitant medications : NO

STUDY COMPLETION/ TERMINATION RECORD

- 1) Did the Subject complete the study : Yes
- 2) Date of last dose of study medication taken : -