Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 09:53:24 GMT)

CTRI Number	CTRI/2020/05/025485 [Registered on: 30/05/2020] - **Trial Registered Prospectively**
Last Modified On	29/05/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Ayurveda
Study Design	Non-randomized, Active Controlled Trial
Public Title of Study	the effect of Guduchi (Tinospora cordifolia) as a prophylactic measure among high risk population (Health Care Workers/Containment Zone Population) exposed to COVID-19
Scientific Title of Study	A prospective non-randomized open labeled controlled interventional study on the effect of Guduchi (Tinospora cordifolia) as a prophylactic measure among high risk population (Health Care Workers/Containment Zone Population) exposed to COVID-19

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr P V V Prasad
Designation	Assistant Director-In charge
Affiliation	NIIMH-CCRAS, Ministry of AYUSH
Address	Survey No.314, Revenue Board Colony, Gaddiannaram, Hyderabad-500036, Telangana, INDIA Survey No.314, Revenue Board Colony, Gaddiannaram, Hyderabad-500036, Telangana, INDIA Hyderabad TELANGANA 500036 India
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Source of Monetary or Material Support

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> CCRASNIIMH,National Institute of Indian Medical Heritage (CCRAS), Survey No.314, Revenue Board Colony, Gaddiannaram, Hyderabad-500036,

Primary Sponsor

Primary Sponsor Details	
Name	CCRASNIIMH
Address	National Institute of Indian Medical Heritage (CCRAS), Survey No.314, Revenue Board Colony, Gaddiannaram, Hyderabad-500036,
Type of Sponsor	Research institution

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
DR PVV Prasad	CCRAS-NIIMH	National Institute of Indian Medical Heritage (CCRAS), Survey No.314, Revenue Board Colony, Gaddiannaram, Hyderabad-500036, Hyderabad TELANGANA	040-24067388 prasadpeyyala@yahoo.co.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee	Approved	30/04/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	2. Subjects who are froma community where at least 1 confirmed case is already identified.

Intervention / Comparator Agent

Type	Name	Details
Intervention	GUDUCHI CAPSULE	GUDUCHI CAPSULE-250 mg X 2 capsules b.d, for one month
Comparator Agent	Standard Prophylactic Care	Standard Prophylactic Care recommended by Government of Telangana Health authorities

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	68.00 Year(s)
Gender	Both

Details	1. Adult Male or Female subjects above the age of 18 years to 68 years of age 2. Subjects who are froma community where at least 1 confirmed case is already identified. 3. Subjects who are ready to provide written/digital informed consent and who are willing to participate and follow the protocol requirements of the clinical study

Exclusion Criteria

Exclusion Criteria	
Details	1. Pregnant and Lactating females 2. Known cases of uncontrolled Diabetes and Hypertension. 3. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening 4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis, Cancer etc. 5. Subjects taking Steroid treatment and or any kind of immunosuppressive therapy 6. Subjects participating in any other clinical study or having participated in any other study 1 month prior to screening in the present study. 7. Subjects having a past history of allergy to any medicine that is part of the Ayurvedic intervention. 8. Other conditions, which in the opinion of the investigators, makes the patient unsuitable for enrolment or could interfere with his participation in, and completion of the protocol

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
1. Comparative assessment of occurrence of COVID-19 infection in healthy volunteers in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care	0 15 30 45 days

Secondary Outcome

Outcome	Timepoints
a) Assessment of subjects not requiring hospitalization b) Severity of symptoms of hospitalized patients in wards c) Patients requiring ICU admission / Ventilator support 3. Safety assessment by evaluation of occurrence of AE/SAE due to consumption of Ayurveda Intervention	0 15 30 45 days

Target Sample Size	**Total Sample Size=**5000 **Sample Size from India=**5000 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2/ Phase 3
Date of First Enrollment (India)	29/06/2020
Date of First	No Date Specified

Enrollment (Global)	
Estimated Duration of Trial	**Years=**0 **Months=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	In view of no vaccine /treatment available for COVID-19 infection as on date, there is a need to investigate the potential intervention. Although there are lot of Clinical studies are ongoing all over the world, there is a scope for Traditional systems of Medicine also in these types of pandemic conditions, where masses of population are affected. It is imperative that to cater to such a huge population there should be a research on Traditional systems of medicine also, as these systems are co-existing with the lifestyles of the people in that particular geographical region. In Classical textbooks of these traditional medicines such type of outbreaks have been explained and their possible treatment. This is a attempt to investigate the role of Ayurveda intervention in prophylaxis of COVID-19 infection to save the healthy population from being infected.