



Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 08:45:00 GMT)

CTRI Number	CTRI/2020/05/025485 [Registered on: 30/05/2020] - Trial Registered Prospectively	
Last Modified On	12/10/2020	
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
	Phone	040-24067388
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr P V V Prasad
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> 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 from a 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 from a 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
Secondary 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	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
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 Enrollment (Global)	No Date Specified	
Estimated Duration of	Years=0	



Trial	Months=3 Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NIL
Brief Summary	<p>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.</p>