



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 09:57:42 GMT)

CTRI Number	CTRI/2020/05/025088 [Registered on: 09/05/2020] - Trial Registered Prospectively	
Last Modified On	08/05/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Drug Ayurveda Preventive	
Study Design	Randomized, Parallel Group Trial	
Public Title of Study	Study of GUDUCHI TABLET on healthy individuals to prevent covid 19.	
Scientific Title of Study	Observational Study of GUDUCHI TABLET intake as a preventive measure in pandemic of COVID-19 – An open label, Randomized, Controlled, Prospective, Interventional, Community-based Clinical study on healthy subjects	
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 B vankatshwarlu
	Designation	Research officer(Ayu)
	Affiliation	Regional ayurveda research institute vijayawada
	Address	Regional Ayurveda Research Institute for Skin disorders, New Rajeev nagar, Payakapuram Vjayawada. Krishna ANDHRA PRADESH 520015 India
	Phone	6301340787
	Fax	
	Email	drcvenkat@rediffmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr B vankatshwarlu
	Designation	Research officer(Ayu)
	Affiliation	Regional ayurveda research institute vijayawada
	Address	Regional Ayurveda Research Institute for Skin disorders, New Rajeev nagar, Payakapuram Vjayawada. Krishna ANDHRA PRADESH 520015 India
	Phone	6301340787
	Fax	
	Email	drcvenkat@rediffmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr B vankatshwarlu
	Designation	Research officer(Ayu)
	Affiliation	Regional ayurveda research institute vijayawada
	Address	Regional Ayurveda Research Institute for Skin disorders, New Rajeev nagar, Payakapuram Vjayawada. Krishna ANDHRA PRADESH 520015



	India			
Phone	6301340787			
Fax				
Email	drcvenkat@rediffmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Ministry of Ayush government of India			
Primary Sponsor	Primary Sponsor Details			
Name	central council for rsearch in ayurvedic sciences			
Address	61-65, opp. D Block, Janakpuri Institutional Area, Janakpuri, New Delhi, Delhi 110058			
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 K Anumol	Regional Ayurveda research institute Vijayawada	Regional Ayurveda research institute for skin disorders , new rajeev nagar Vijayawada Krishna ANDHRA PRADESH	8075021635 dranumolk@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional ethics committee Vijayawada	Approved	05/05/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Participant will select from area where atleast one covid 19 positive patient available	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Guduchi tablet	Tab Guduchi 500mg twice daily for one month	
	Comparator Agent	nil	nil	
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. 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	<p>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</p>	
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Not Applicable	
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	15th day, 30th day, 45th day
Secondary Outcome	Outcome	Timepoints
	<p>1. Comparative assessment of severity of Covid-19 infection in subjects taking GUDUCHI TABLET and those not taking it in following situations: a) Assessment of subjects not requiring hospitalization b) Severity of symptoms of hospitalized patients in wards c) Patients requiring ICU admission / Ventilator support 2. Global assessment of overall change as per the investigator (Efficacy assessment)</p>	15th day , 30th day and 45 th day
Target Sample Size	<p>Total Sample Size=1200 Sample Size from India=1200 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</p>	
Phase of Trial	Phase 1/ Phase 2	
Date of First Enrollment (India)	20/05/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	<p>Years=0 Months=6 Days=0</p>	
Recruitment Status of Trial (Global)	Not Applicable	



Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	nil
Brief Summary	<p>There is no available vaccine against COVID-19 infections and no drug with proven clinical efficacy, although there are several candidates that might be effective in prevention or treatment. Encouragingly, the response from the research community to the pandemic of Coronavirus disease 2019 (COVID-19) has been vigorous. Guduchi is Rasayana drug which improves immunity. In This study will give Guduchi tab 500mg twice daily for one month to healthy individuals to prevent Covid 19. We are selecting the patient from community where atleast one covid 19 patient is present. The possible outcomes of the study will be Primary outcome Comparative assessment of occurrence of COVID-19 infection in healthy volunteers in community having at</p>



least 1 confirmed case already identified with control arm of Standard Prophylactic

Care and Secondary outcomev will be

Comparative assessment of severity of Covid-19 infection in subjects taking

Guduchi Tablet and those not taking it in following situations:

- a) **Assessment of subjects not requiring hospitalization**
 - b) **Severity of symptoms of hospitalized patients in wards**
 - c) **Patients requiring ICU admission / Ventilator support**
2. **Global assessment of overall change as per the investigator (Efficacy assessment)**
 3. **Safety assessment by evaluation of occurrence of AE/SAE due to consumption**



of Ayurveda Intervention