



Clinical Trial Details (PDF Generation Date :- Fri, 14 Aug 2020 11:27:02 GMT)

<b>CTRI Number</b>	CTRI/2020/05/025488 [Registered on: 31/05/2020] - <b>Trial Registered Prospectively</b>		
<b>Last Modified On</b>	28/05/2020		
<b>Post Graduate Thesis</b>	No		
<b>Type of Trial</b>	Interventional		
<b>Type of Study</b>	Ayurveda		
<b>Study Design</b>	Randomized, Parallel Group Trial		
<b>Public Title of Study</b>	Clinical study on Guduchi Ghana Vati as a preventive remedy in pandemic of COVID-19		
<b>Scientific Title of Study</b>	An Open label, Multi centric, Randomized, Comparative, Prospective, Interventional Community based Clinical Study to Evaluate Safety and Efficacy of Guduchi Ghana Vati as a Preventive Remedy on Healthy Individuals in Pandemic of COVID-19		
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>	
	NIA-CVD-19/2020/01 Version 1.0 Dated 20th May 2020	Protocol Number	
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>		
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
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<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	National Institute of Ayurveda			
<b>Address</b>	Madhav Vilas Palace, Jorawar Singh Gate, Amer Road JAIPUR - 302002 (RAJASTHAN) INDIA			
<b>Type of Sponsor</b>	Government medical college			
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	NIL	NIL		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	Prof Dr Sanjeev Sharma	National Institute of Ayurveda	OPD No 1, Department of Shalya Tantra, Ground floor, Madhav Vilas Palace, Jorawar Singh Gate, Amer Road JAIPUR - 302002 (RAJASTHAN) INDIA Jaipur RAJASTHAN	09418079691 profsanjeevhp@gmail.com
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	Institutional Ethics Committee National Institute of Ayurveda Madhav Vilas Palace, Amer Road, Jaipur	Approved	22/05/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>	<b>Date</b>		
	Not Applicable	No Date Specified		
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>	<b>Condition</b>		
	Healthy Human Volunteers	Healthy Human Volunteers		
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Guduchi Ghana Vati	Each Guduchi Ghana Vati contains Guduchi Ghana (Tinospora cordifolia) 500 mg with preservatives and excipients Dosage and Treatment Duration: 2 tablets twice daily orally after meals with water for 45 days	
	Comparator Agent	NIL	Dosage and Treatment Duration: Subjects in this group will not be given any medicine	



<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>	
	<b>Age From</b>	18.00 Year(s)
	<b>Age To</b>	70.00 Year(s)
	<b>Gender</b>	Both
	<b>Details</b>	<p>1. Healthy, Male or Female subjects between the age group of 18 years to 70 years (both inclusive). Healthy individuals will be considered as those who do not have any acute medical condition or chronic medical/surgical condition that requires either immediate or continuous medical monitoring or treatment.</p> <p>2. Subjects who are ready to provide written informed consent and who are ready to willingly participate and follow the protocol requirements of the clinical study.</p>
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	<p>1. Pregnant and Lactating females</p> <p>2. Subjects who have been confirmed of having COVID-19 and have been isolated for its treatment. Subjects having recently suffered and recovered of COVID-19 will also be excluded from the study</p> <p>3. Subjects having any medical or surgical condition that would require immediate medical or surgical intervention at the time of screening</p> <p>4. Subjects having immune compromised status like HIV, Hepatitis, Tuberculosis and Cancer etc.</p> <p>5. Subjects taking steroid treatment and or any kind of immunosuppressive therapy</p> <p>6. Subjects participating in any other clinical study or having participated in any other study 3 months prior to screening in the present study.</p> <p>7. Other conditions, which in the opinion of the investigators makes the patient unsuitable for enrolment or could interfere in adherence to of the study protocol</p>
<b>Method of Generating Random Sequence</b>	Computer generated randomization	
<b>Method of Concealment</b>	Not Applicable	
<b>Blinding/Masking</b>	Open Label	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Comparative assessment of incidence of COVID-19 in subjects taking GUDUCHI GHANA VATI and those not taking it over a period of 45 days	(day-5, day 0, day-15, day-30, day-45)
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	<p>1. Comparative assessment of incidence of other non COVID-19 infections in both the groups</p> <p>2. Comparative assessment of severity of COVID-19 in both the groups.</p> <p>3. Comparative assessment of number of subjects requiring hospitalization, number of days of hospitalization, ICU admission, Ventilator support and mortality rate.</p> <p>4. Global assessment of overall change as per the investigator</p> <p>5. Safety assessment by evaluation of occurrence of AE/SAE</p>	(day-5, day 0, day-15, day-30, day-45)



<b>Target Sample Size</b>	<p><b>Total Sample Size=12000</b>  <b>Sample Size from India=12000</b>  <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b>  <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b></p>
<b>Phase of Trial</b>	Phase 2/ Phase 3
<b>Date of First Enrollment (India)</b>	03/06/2020
<b>Date of First Enrollment (Global)</b>	No Date Specified
<b>Estimated Duration of Trial</b>	<p><b>Years=0</b>  <b>Months=8</b>  <b>Days=0</b></p>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Not Yet Recruiting
<b>Publication Details</b>	NOT YET DONE
<b>Brief Summary</b>	<p>It is an open label, multi centric, randomized, comparative, prospective, interventional community based clinical study to evaluate safety and efficacy of Guduchi Ghana Vati as a preventive remedy on healthy individuals in pandemic of COVID-19. The trial will be completed in 12000 subjects in 6 centers across India. Subjects from group A will be given Guduchi Ghana Vati in a dose of two tablets twice daily orally after meals with water for 45 days. Subjects from group B will not be given any intervention. The primary objectives of the study will be comparative assessment of incidence of COVID-19 in subjects taking GUDUCHI GHANA VATI and those not taking it over a period of 45 days. Secondary objectives will be comparative assessment of incidence of other non COVID-19 infections in subjects taking GUDUCHI GHANA VATI and those not taking it over a period of 45 days, comparative assessment of severity of COVID-19 (when it occurs) in subjects taking GUDUCHI GHANA VATI and those not taking it. Severity will be graded as per the attached ordinal scale for clinical improvement of COVID-19 published by WHO, comparative assessment of number of subjects requiring hospitalization, number of days of hospitalization, number of subjects requiring ICU admission and number of subjects requiring Ventilator support and mortality rate, global assessment of overall change as per the investigator and safety assessment by evaluation of occurrence of AE/SAE on day-5, day 0, day-15, day-30 and day-45.</p>