



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 17:07:33 GMT)

<b>CTRI Number</b>	CTRI/2020/05/025429 [Registered on: 29/05/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	10/07/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Ayurveda	
<b>Study Design</b>	Non-randomized, Active Controlled Trial	
<b>Public Title of Study</b>	effect of Ashwagandha (Withania somnifera) as a prophylactic measure among high risk population (Health Care Workers/Containment Zone Population) exposed to COVID-19	
<b>Scientific Title of Study</b>	A prospective non-randomized open labeled controlled interventional study on the effect of Ashwagandha (Withania somnifera) as a prophylactic measure among high risk population (Health Care Workers/Containment Zone Population) exposed to COVID-19	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	Dr T Saketh Ram
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<b>Details Contact Person (Public Query)</b>	<b>Details Contact Person (Public Query)</b>	
	<b>Name</b>	Dr PVV Prasad
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> ccrasniimh			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	CCRASNIIMH			
<b>Address</b>	National Institute of Indian Medical Heritage (CCRAS), Survey No.314, Revenue Board Colony, Gaddiannaram, Hyderabad-500036,			
<b>Type of Sponsor</b>	Research institution			
<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>
	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 040-24067388 niimh.hyderabad@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 Ethical Committee	Approved	30/04/2020	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 volunteers in community having at least 1 confirmed case already identified	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	ASHWAGANDHA	ASHWAGANDHA CAPSULE + Standard Prophylactic Care recommended by Government of TelanganaHealth authorities	
	Comparator Agent	Standard Prophylactic Care	Standard Prophylactic Care recommended by Government of TelanganaHealth authorities	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	18.00 Year(s)		
	<b>Age To</b>	68.00 Year(s)		
	<b>Gender</b>	Both		



	<b>Details</b>	1. Adult Male or Female subjects above the age of 18 years to 68 years 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
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	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
<b>Method of Generating Random Sequence</b>	Not Applicable	
<b>Method of Concealment</b>	Not Applicable	
<b>Blinding/Masking</b>	Open Label	
<b>Primary Outcome</b>	<b>Outcome</b> <span style="float: right;"><b>Timepoints</b></span>	
	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 day
<b>Secondary Outcome</b>	<b>Outcome</b> <span style="float: right;"><b>Timepoints</b></span>	
	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 day
<b>Target Sample Size</b>	<b>Total Sample Size=5000</b> <b>Sample Size from India=5000</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>	
<b>Phase of Trial</b>	Phase 2/ Phase 3	
<b>Date of First Enrollment (India)</b>	10/06/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of</b>	Years=0	



<b>Trial</b>	<b>Months=3</b> <b>Days=0</b>
<b>Recruitment Status of Trial (Global)</b>	Not Applicable
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment
<b>Publication Details</b>	6. Acharya YT, editor. Charaka Samhita (Ch. Chi. 3/). Varanasi: Chowkhamba Surbharati; 2000 7. Peruski, A. H., & Peruski, L. F., Jr (2003). Immunological methods for detection and identification of infectious disease and biological warfare agents. Clinical and diagnostic laboratory immunology, 10(4), 506–513. <a href="https://doi.org/10.1128/cdli.10.4.506-513.2003">https://doi.org/10.1128/cdli.10.4.506-513.2003</a> 8. KamWa Chan, Vivian Taam Wong, and Sydney Chi Wai Tang, COVID-19: An Update on the Epidemiological, Clinical, Preventive and Therapeutic Evidence and Guidelines of Integrative Chinese–Western Medicine for the Management of 2019 Novel Coronavirus Disease, The American Journal of Chinese Medicine, Vol. 48, No. 3, 1–26 , Published 13 March 2020, DOI: 10.1142/S0192415X20500378
<b>Brief Summary</b>	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.