



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 18:05:31 GMT)

<b>CTRI Number</b>	CTRI/2020/06/025561 [Registered on: 03/06/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	13/10/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Observational	
<b>Type of Study</b>	Prospective Open label Observational study	
<b>Study Design</b>	Other	
<b>Public Title of Study</b>	Effect of Ayurvedic medicine in the Prophylaxis for COVID-19 of AYUSH healthcare workers , Dept of AYUSH, TS & CCRAS- NIIMH, Hyderabad.	
<b>Scientific Title of Study</b>	Prospective open label observational study on the effect of AYUSH-64, Samshamani vati & Chyavanprash- (Ayurvedic Raksha Kit-I) as Prophylactic measure among AYUSH healthcare workers working in the vicinity of COVID -19 facilities.	
<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 Srikanth Babu Perugu
	<b>Designation</b>	Professor and HOD Department of Kayachikitsa
	<b>Affiliation</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Department of AYUSH Govt. of Telangana– Ayurveda & CCRAS-NIIMH, Hyderabad			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
<b>Name</b>	Department of AYUSH Govt of Telangana Ayurveda CCRASNIIMH Hyderabad			
<b>Address</b>	Department of Ayush, Opposite passport office, Government Of Telangana			
<b>Type of Sponsor</b>	Research institution and hospital			
<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>
	DrPSrikanth Babu	Dr. B.R.K.R. Government Ayurvedic College	Department of Kayachikitsa, SR Nagar Hyderabad TELANGANA Hyderabad TELANGANA	9849463878 drperuugu@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 CCRAS-NIIMH	Approved	27/05/2020	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		Ayush health workers in vicinity of COVID 19 facility	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	RAKSHA KIT-1	Chavanprash, 10 grams once aday Samshamani vati 250 mg 2 times a day & AYUSH 64 500 mg 2 times a day	
	Comparator Agent	Standard Prophylactic Care	Standard Prophylactic Care recommended by Government of Telangana Health 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. AYUSH health care workers working within the facilities of COVID-19 duties.   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>	Exclusion criteria: 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>	Not Applicable	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis Police personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care	0 day and 40th day Comparative assessment of occurrence of COVID-19 infection in healthy volunteers vis AYUSH personal in community having at least 1 confirmed case already identified with control arm of Standard Prophylactic Care
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	General health status of those who are taking Ayurveda preventive medicine.	3 months
<b>Target Sample Size</b>	<b>Total Sample Size=500</b> <b>Sample Size from India=500</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>	15/06/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=6</b> <b>Days=0</b>	
<b>Recruitment Status of</b>	Not Applicable	



<b>Trial (Global)</b>	
<b>Recruitment Status of Trial (India)</b>	Open to Recruitment
<b>Publication Details</b>	nil
<b>Brief Summary</b>	<p>in view of the no treatment available for COVID-19 infection as on date, there is a need to investigate the potential of ayurvedic preventive medicine. Classical texts of Ayurveda have emphasized the out break of such pandemics in the name of "Janapadodhwamsa" and narrated a specific preventive protocol. This is an attempt to observe the preventiive role of Ayurveda protocol in ayush personel / Healthy volunteers working in the vicinity of covid-19 facilities.</p>