



Clinical Trial Details (PDF Generation Date :- Sun, 13 Jun 2021 02:29:33 GMT)

CTRI Number	CTRI/2020/05/025493 [Registered on: 31/05/2020] - Trial Registered Prospectively	
Last Modified On	30/05/2020	
Post Graduate Thesis	No	
Type of Trial	Observational	
Type of Study	Cohort Study	
Study Design	Other	
Public Title of Study	Effect of Ayurvedic medicine in the Prophylaxis for COVID-19 of Police personnel Dept of AYUSH, TS & CCRAS- NIIMH, Hyderabad.	
Scientific Title of Study	Prospective Open label Observational study on the Effect of Chyawanprash, Samshamani vati & Haritaki (Raksha Kit) as Prophylactic measure among police personnel working in the vicinity of COVID -19 facilities	
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 Madikonda Praveen kumar
	Designation	Assoc. Professor, Department of Panchakarma
	Affiliation	Dr. B.R.K.R. Government Ayurvedic College
	Address	Department of Panchakarma, Dr. B.R.K.R. Government Ayurvedic College SR Nagar Hyderabad Hyderabad TELANGANA 500038 India
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Department of AYUSH Govt. of Telangana– Ayurveda & CCRAS-NIIMH, Hyderabad			
Primary Sponsor	Primary Sponsor Details			
	Name	Department of AYUSH Govt of Telangana Ayurveda CCRASNIIMH Hyderabad		
	Address	Department of Ayush, Opposite passport office, Government Of Telangana		
	Type of Sponsor	Research institution and hospital		
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
	Madikonda Praveen kumar	Dr BRKR Government Ayurvedic College	Department of Panchakarma, Room number 2 & 5, SR Nagar Hyderabad TELANGANA	9849271601 pkmadikonda@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethical Committee CCRAS-NIIMH, Hyderabad	Approved	27/05/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		police personnel working in the vicinity of Covid 19 Facilitites	
Intervention / Comparator Agent	Type	Name	Details	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	68.00 Year(s)		
	Gender	Both		
	Details	2. Police personnel working within the facilities of COVID-19 duties. 3. Subjects who are from a community where at least 1 confirmed case is already identified. 4. 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	Not Applicable				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>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</td> <td>3 months</td> </tr> </tbody> </table>	Outcome	Timepoints	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	3 months
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Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>General health status of those who are taking Ayurveda preventive medicine.</td> <td>3 months</td> </tr> </tbody> </table>	Outcome	Timepoints	General health status of those who are taking Ayurveda preventive medicine.	3 months
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Target Sample Size	Total Sample Size=1500 Sample Size from India=1500 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)	15/06/2020				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	Years=0 Months=6 Days=0				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Not Yet Recruiting				
Publication Details	NIL				
Brief Summary	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 police personel / Healthy volunteers working in the vicinity of covid-19 facilities.				