



Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 16:19:36 GMT)

<b>CTRI Number</b>	CTRI/2020/04/024731 [Registered on: 20/04/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	18/04/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Ayurveda Homeopathy	
<b>Study Design</b>	Single Arm Trial	
<b>Public Title of Study</b>	Study to Evaluate Preventive Effect of Ayurveda and Homeopathy Treatment in COVID 19	
<b>Scientific Title of Study</b>	Evaluation of Effect of Composite AYUSH Treatment as Prophylaxis of 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>	
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	<b>Designation</b>	Dean and Principal
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> Parul Institute of Ayurved			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	Superintendent		
	<b>Address</b>	Parul Ayurved Hospital, Parul Institute of Ayurved, Parul University, AP Limda, Tal Waghodia, Vadodara, Gujarat 391760		
	<b>Type of Sponsor</b>	Private 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>
	Dr Hemant Toshikhane	Parul Ayurved Hospital	Ground Floor, Parul Ayurved Hospital, Parul Institute of Ayurved, Parul University, AP Limda, Tal Waghodia, Vadodara GUJARAT	8469496525 drhemantt@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 for Human Research	Approved	19/03/2020	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 who have high chances of exposure to COVID 19 patients	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	Samshamani Vati (500 mg twice daily after food with warm water for 15 days), Sudarshan Ghana Vati (250 mg thrice daily after food with warm water for 15 days), Khadiradi Vati (250 mg twice daily for chewing for 15 days), Murrchhita Tila Taila (for Nasya (nasal instillation) 2 drops in each nostril in morning and evening for 15 days), Aesenic Album 30 (4 tablets before lunch for 3 days)	For 15 days	
	Comparator Agent	Not Applicable	Not Applicable	
<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>	Subjects who are not suffering from active illness due to infection at the time of inclusion	
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>	
	<b>Details</b>	<ol style="list-style-type: none"> <li>1. Subjects suffering from active illness due to infection at the time of inclusion.</li> <li>2. Subjects suffering from uncontrolled DM, HTN etc.</li> <li>3. Subjects who are known cases of immune-compromised or autoimmune condition such as HIV.</li> <li>4. Pregnant and lactating women</li> </ol>
<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>	<b>Timepoints</b>
	Episodes and severity of symptoms of respiratory tract infection (cold, sore throat, dry cough, breathlessness) in subjects who may get direct or indirect exposure to COVID 19 during lockdown in March and April 2020	From Baseline till the end of 15 days
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Incidence of COVID 19 infection in study population	From Baseline till the end of 15 days
	Requirement of treatment for symptoms developed, if any, during study period	From Baseline till the end of 15 days
	Analysis of adverse events, if any	From Baseline till the end of 15 days
<b>Target Sample Size</b>	<b>Total Sample Size=50</b> <b>Sample Size from India=50</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 3	
<b>Date of First Enrollment (India)</b>	24/04/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</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>	Not Yet Recruiting	
<b>Publication Details</b>	Nil	
<b>Brief Summary</b>	<p>The COVID 19 outbreak has been declared as pandemic by the world health organisation. In view of lack of precise treatment or vaccine, the incidence and mortality due to the infection remain high and are very high. Ayurveda explains many medications and treatments in the management of febrile illnesses (Jwara) and diseases of respiratory system (Pranavaha Srota) which are being practised since many years and are proven effective. Hence it is high time to evaluate its effect as a preventive measure in symptoms of respiratory system infection seen in COVID 19 patients. Ayurveda explains many medications and treatments in the management of febrile illnesses (Jwara) and diseases of respiratory system (Pranavaha Srota) which are being practised since many years and are proven effective. Hence it is high time to evaluate its effect as a preventive measure in symptoms of respiratory system infection seen in COVID 19 patients. Rasayana is the Rejuvenation branch of Ayurvedic medicine. Rasayana treatments were traditionally utilized after a period where the body was worn-down or depleted. Rasayana therapies are also used to remedy old age, before the term 'anti-ageing', there was Rasayana. Many classical formulations mentioned in Ayurvedic classic are excellent Rasayana medicines which can be used in treatment of various diseases including Jwara, Kasa, Kshaya. SamshamaniVati, KhadiradiVati, Dashmoola katutrayadi GhanVati are such medicines which can be useful in this condition. Nasya with AnuTala in PralimarshaMatra (2 drops) is a remedy mentioned in Dinacharya that has shown beneficial effects in many URTI conditions. Arsenic album 30 a homeopathic medicine that is claimed to be beneficial in prevention from COVID 19 infection.</p>	