



Clinical Trial Details (PDF Generation Date :- Sat, 03 Jun 2023 10:14:59 GMT)

CTRI Number	CTRI/2020/04/024731 [Registered on: 20/04/2020] - Trial Registered Prospectively	
Last Modified On	18/04/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Ayurveda Homeopathy	
Study Design	Single Arm Study	
Public Title of Study	Study to Evaluate Preventive Effect of Ayurveda and Homeopathy Treatment in COVID 19	
Scientific Title of Study	Evaluation of Effect of Composite AYUSH Treatment as Prophylaxis of COVID 19	
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 Hemant Toshikhane
	Designation	Dean and Principal
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Shailesh Deshpande
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Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Harish Daga
	Designation	Lecturer, Shalya Tantra
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Parul Institute of Ayurved			
Primary Sponsor	Primary Sponsor Details			
	Name	Superintendent		
	Address	Parul Ayurved Hospital, Parul Institute of Ayurved, Parul University, AP Limda, Tal Waghodia, Vadodara, Gujarat 391760		
	Type of Sponsor	Private medical college		
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
	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
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee for Human Research	Approved	19/03/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Healthy Human Volunteers		Healthy Human Volunteers who have high chances of exposure to COVID 19 patients	
Intervention / Comparator Agent	Type	Name	Details	
	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	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	70.00 Year(s)		



Gender	Both	
Details	Subjects who are not suffering from active illness due to infection at the time of inclusion	
Exclusion Criteria	Exclusion Criteria	
	Details	<ol style="list-style-type: none"> 1. Subjects suffering from active illness due to infection at the time of inclusion. 2. Subjects suffering from uncontrolled DM, HTN etc. 3. Subjects who are known cases of immune-compromised or autoimmune condition such as HIV. 4. Pregnant and lactating women
Method of Generating Random Sequence	Not Applicable	
Method of Concealment	Not Applicable	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	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
Secondary Outcome	Outcome	Timepoints
	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
Target Sample Size	Total Sample Size=50 Sample Size from India=50 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 3	
Date of First Enrollment (India)	24/04/2020	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=0 Months=3 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Not Yet Recruiting	
Publication Details	Nil	
Brief Summary	<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 AnuTalla 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>	