



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 17:18:29 GMT)

CTRI Number	CTRI/2020/06/025844 [Registered on: 12/06/2020] - Trial Registered Prospectively	
Last Modified On	04/06/2021	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Homeopathy	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	Pre-Identified Homoeopathic Medicines In Asymptomatic Covid -19 Individuals Receiving Standard Treatment Protocol	
Scientific Title of Study	Comparative Effectiveness Of Pre-Identified Homoeopathic Medicines In Asymptomatic Covid -19 Individuals Receiving Standard Treatment Protocol–An Open Label, Randomised, Placebo Controlled Trial	
Secondary IDs if Any	Secondary ID	Identifier
	NIL	NIL
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator	
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Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Anil Khurana
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Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Central Council for Research in Homoeopathy, New Delhi			
Primary Sponsor	Primary Sponsor Details			
	Name	Central Council for Research in Homoeopathy New Delhi		
	Address	61-65, Institutional area, opp D block Janakpuri		
	Type of Sponsor	Research institution		
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 Sunita Tomar	Government Homoeopathic Medical College and Hospital	Room no. 2 Medical Superintendent AYUSH Parisar, Kallusot Dam, MACT hills, pin 462003 Bhopal MADHYA PRADESH	826875470 dr.sunitatomar@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethical Committee -CCRH	Approved	03/06/2020	No
Regulatory Clearance Status from DCGI	Status		Date	
	Not Applicable		No Date Specified	
Health Condition / Problems Studied	Health Type		Condition	
	Patients		Coronavirus as the cause of diseases classified elsewhere	
Intervention / Comparator Agent	Type	Name	Details	
	Intervention	Homoeopathic medicine	Arsenicum album 30- four pills twice daily for seven days, Bryonia 30- four pills twice daily for seven days, Camphora 1M- four pills twice daily for four days alongwith Standard treatment protocol	
	Comparator Agent	Placebo four pills twice daily for seven days	Placebo alongwith Standard treatment protocol	
Inclusion Criteria	Inclusion Criteria			
	Age From	18.00 Year(s)		
	Age To	65.00 Year(s)		
	Gender	Both		
	Details	COVID 19 confirmed individuals who are Asymptomatic and receiving standard treatment protocol Age 18 years & above and of both sexes Willing to sign written informed consent 		
Exclusion Criteria	Exclusion Criteria			
	Details	Pregnant women or lactating mothers Immunocompromised persons on basis of medical history		



	Symptomatic COVID-19 individuals Not willing to give informed consent				
Method of Generating Random Sequence	Computer generated randomization				
Method of Concealment	An Open list of random numbers				
Blinding/Masking	Open Label				
Primary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>An individual remaining asymptomatic/ becoming symptomatic / virologically negative during the maximum duration of incubation period (21 days)/ till the patient is at CCC as per the standard treatment protocol (ICMR)</td> <td>At 5th day, 10th day, 15th day</td> </tr> </tbody> </table>	Outcome	Timepoints	An individual remaining asymptomatic/ becoming symptomatic / virologically negative during the maximum duration of incubation period (21 days)/ till the patient is at CCC as per the standard treatment protocol (ICMR)	At 5th day, 10th day, 15th day
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Secondary Outcome	<table border="1"> <thead> <tr> <th>Outcome</th> <th>Timepoints</th> </tr> </thead> <tbody> <tr> <td>1. Time to become virologically negative through RT-PCR. 1. Time to appearance of clinical symptoms of COVID-19.</td> <td>At 5th day, 10th day, 15th day</td> </tr> </tbody> </table>	Outcome	Timepoints	1. Time to become virologically negative through RT-PCR. 1. Time to appearance of clinical symptoms of COVID-19.	At 5th day, 10th day, 15th day
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Target Sample Size	Total Sample Size=200 Sample Size from India=200 Final Enrollment numbers achieved (Total)=0 Final Enrollment numbers achieved (India)=200				
Phase of Trial	Phase 2/ Phase 3				
Date of First Enrollment (India)	22/06/2020				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	Years=0 Months=2 Days=0				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Completed				
Publication Details	None yet.				
Brief Summary	<p>Asymptomatic carriers of infectious diseases pose a significant challenge in mitigation efforts, since they display no symptoms but can still be contagious and pass on the disease to other people. For clinical management with symptomatic COVID19 cases there are array of drugs approved and further trials are ongoing. During this COVID19 outbreak, a group of experts (SAB, CCRH) discussed the sign and symptoms observed in COVID-19 patients of Wuhan, China from the recent publication of Lancet, "Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China". Analysis of these symptoms was made to find out the genus epidemicus. Arsenicum album was emerged as Genus epidemicus. This has also been advised for prevention of ILL. In Hongkong, Homeopaths have found Bryonia alba mostly indicated in Covid 19 patients. In another unpublished case series treated by Homeopathy in Iran and other countries prescribed Camphora 1M with encouraging outcomes. This openlabel randomized placebo controlled trial will be able to estimate the comparative effect of pre identified homeopathic medicines in asymptomatic covid19 patients receiving standard treatment protocol.</p>				