



Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 16:06:46 GMT)

CTRI Number	CTRI/2020/05/024986 [Registered on: 04/05/2020] - Trial Registered Prospectively	
Last Modified On	03/05/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Homeopathy	
Study Design	Single Arm Trial	
Public Title of Study	HOMOEOPATHY IN PREVENTION OF COVID-19	
Scientific Title of Study	EFFECTIVENESS OF ARSENICUM ALBUM 30C IN PREVENTION OF COVID-19 IN INDIVIDUALS RESIDING IN HOSPOTS OF RED ZONES IN DELHI- A PROSPECTIVE COHORT STUDY	
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 (Scientific Query)	Details Contact Person (Scientific Query)
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Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Raj K Manchanda
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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		
	Address	61-65, Sewa Marg, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 61-65, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058		
	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 Debadatta Nayak	Hot spots of Covid -19 in Delhi	Central Council for Research in Homoeopathy 61-65, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 South West DELHI	09873404012 drdnayak@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee-CCRH	Approved	02/05/2020	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	Homoeopathic medicine Arsenic album 30c will be given to population residing in hot spots of Red zones of Covid-19 out break. The medicine will be given as medicated globules. 2-4 medicated globules will be given twice daily for 7 days.	
Inclusion Criteria	Inclusion Criteria			
	Age From	1.00 Year(s)		
	Age To	80.00 Year(s)		
	Gender	Both		
	Details	<ul style="list-style-type: none"> • Suspected cases of Covid 19 infection who are asymptomatic • Persons residing in residing in hot spots 		



	of Delhi.				
	<ul style="list-style-type: none"> • Age 1 year & above • Both gender • Willing to give verbal informed consent (keeping in view contagious nature of disease) 				
Exclusion Criteria	Exclusion Criteria				
Details	<ul style="list-style-type: none"> • Pregnant women • Lactating mothers • Immunocompromised individuals on basis of medical history • Symptomatic (similar to COVID-19) cases at quarantine zone. • Not willing to give verbal informed consent 				
Method of Generating Random Sequence	Not Applicable				
Method of Concealment	Not Applicable				
Blinding/Masking	Not Applicable				
Primary Outcome	<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: center;">Outcome</th> <th style="text-align: center;">Timepoints</th> </tr> </thead> <tbody> <tr> <td>Confirmation of diagnosis for COVID-19 infection / end of quarantine period as per standard protocol.</td> <td>Every 7th day.</td> </tr> </tbody> </table>	Outcome	Timepoints	Confirmation of diagnosis for COVID-19 infection / end of quarantine period as per standard protocol.	Every 7th day.
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Secondary Outcome	<table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: center;">Outcome</th> <th style="text-align: center;">Timepoints</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> • To compare time to appearance of clinical symptoms of COVID-19 infections. • To compare time to confirmation of diagnosis for COVID-19 (Laboratory findings) </td> <td>Every 7th day.</td> </tr> </tbody> </table>	Outcome	Timepoints	<ul style="list-style-type: none"> • To compare time to appearance of clinical symptoms of COVID-19 infections. • To compare time to confirmation of diagnosis for COVID-19 (Laboratory findings) 	Every 7th day.
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Target Sample Size	<p>Total Sample Size=10000 Sample Size from India=10000 Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</p>				
Phase of Trial	N/A				
Date of First Enrollment (India)	13/05/2020				
Date of First Enrollment (Global)	No Date Specified				
Estimated Duration of Trial	<p>Years=0 Months=6 Days=0</p>				
Recruitment Status of Trial (Global)	Not Applicable				
Recruitment Status of Trial (India)	Not Yet Recruiting				
Publication Details	None yet.				
Brief Summary	The results of the study will be able to estimate the protective effect of <i>Arsenicum album</i> in COVID 19 prevention. If found effective, this could prove to be a vital contribution in public health care for a disease with high mortality. Further the cost-effectiveness of homoeopathy will enable developing countries in controlling such deadly disease effectively.				