



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 18:39:30 GMT)

CTRI Number	CTRI/2020/05/025205 [Registered on: 15/05/2020] - Trial Registered Prospectively	
Last Modified On	20/05/2020	
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Homeopathy	
Study Design	Cluster Randomized Trial	
Public Title of Study	Arsenicum album – 30 as prophylactic for Covid-19	
Scientific Title of Study	Effectiveness of Arsenicum Album 30c in Prevention of Covid-19 in Individuals Residing in Hot Spots of Red Zones– A Multicentric, Randomised, Cluster Level, 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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	Designation	Director General
	Affiliation	CCRH
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Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Debadatta Nayak
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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		
	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 Karthikeyan	Hot spots of Covid -19 in Chennai	Homoeopathy Research Institute for Disabilities, 136,NIEPMD Campus East Coast Road, Muttukadu, Chennai 603112 Chennai TAMIL NADU	8281488685 drkarthikeyanmd@gmail.com
	Dr Debadatta Nayak	Hot spots of Covid -19 in Delhi	61-65, Sewa Marg, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 South West DELHI	09873404012 drdnayak@gmail.com
	Dr Ch Ravender	Hot spots of Covid -19 in Gudivada and Vijaywada	Regional Research Institute for (Homoeopathy) Dr. GGH Medical College Campus, Eluru Road, Gudivada – 521 301 Krishna Dist., Andhra Pradesh State Mob. Krishna ANDHRA PRADESH	9849126380 rrigudivada@gmail.com
	Dr P Hima Bindu	Hot spots of Covid -19 in Hyderabad	Standardisation Unit (Homoeopathy), OUB-32, Street No. 4, Habsiguda, Hyderabad, Tellangana-500007 Hyderabad TELANGANA	9490009899 drdewdrop@gmail.com
	Dr Ashish Mahajan	Hot spots of Covid -19 in Jaipur	Central Research Institute (Homoeopathy), Sector 26, Pratap Nagar, Jaipur Jaipur RAJASTHAN	8527266606 dr.aashishmahajan@gmail.com
	Dr P P Pal	Hot spots of Covid -19	Dr. Anjali Chatterji	8910890779



	in Kolkata	Regional Research In Homoeopathy 50, Rajendra Chatterjee Road, Kolkata-700035 Kolkata WEST BENGAL	justdoit.partha@gmail.com
Dr KC Murleedharan	Hot spots of Covid -19 in Kottayam	National Homoeopathy Research Institute in Mental Health Sachivothamapuram P.O., Kottayam-686 532(Kerala) Kottayam KERALA	9869321223 nhrimh@gmail.com
Dr Lipipushpa Debata	Hot spots of Covid -19 in Lucknow	Homoeopathic Drug Research Institute National Homoeopathic Medical College & Hospital, 1 Viraj Khand, Gomti Nagar, Lucknow Lucknow UTTAR PRADESH	07755014040 drlipi08@gmail.com
Dr Ramesh Bawaskar	Hot spots of Covid -19 in Mumbai	Regional Research Institute (Homoeopathy), Hall no. 4, Shopping centre, Sector-9, CBD, Belapur, Navi Mumbai-400614 Mumbai MAHARASHTRA	9769888743 drbrsb@gmail.com
Dr Subhash Kaushik	Hot spots of Covid -19 in Noida	Dr. D. P. Rastogi Central Research Institute of Homoeopathy A-1/1, Sector 24, NOIDA, Gautambudh Nagar, 201301 (U.P.) Gautam Buddha Nagar UTTAR PRADESH	9810788976 subhashccrh@gmail.com
Dr Vipul R Shatri	Hot spots of Covid -19 in Surat	C.D.Pachchigar Homoeopathic Medical College, Bhatar Road, Nr. Anand Mangal Society, SURAT - 395001 Surat GUJARAT	09824109174 drvipulshastri@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee-CCRH	Approved	11/05/2020	Yes
Institutional Ethics Committee-CDPCHM	Approved	16/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition /

Health Type	Condition



Problems Studied	Healthy Human Volunteers		For prophylaxis of COVID-19
Intervention / Comparator Agent	Type	Name	Details
	Intervention	Arsenicum album 30C	The Arsenicum album 30C will be given to the high risk contact of COVID 19 cases and residing in hotspots of containment zone. The 4 pills of medicine will be given orally twice daily for 7 days.
	Comparator Agent	No intervention.	The control group clusters will receive no treatment. However they will be under observation similar to medicine group.
Inclusion Criteria	Inclusion Criteria		
	Age From	1.00 Year(s)	
	Age To	90.00 Year(s)	
	Gender	Both	
	Details	<ul style="list-style-type: none"> • High risk contacts of Covid 19 infection who are asymptomatic and residing in hotspots. • Age 1 year & above • Both gender • Willing to give verbal informed consent or written informed consent as the situation may be (keeping in view contagious nature of disease) 	
Exclusion Criteria	Exclusion Criteria		
	Details	<ul style="list-style-type: none"> • Pregnant women or lactating mothers • Immunocompromised individuals on basis of medical history. • Symptomatic (similar to COVID-19) cases at quarantine zone. • Not willing to give informed consent/verbal consent. 	
Method of Generating Random Sequence	Stratified randomization		
Method of Concealment	Centralized		
Blinding/Masking	Not Applicable		
Primary Outcome	Outcome	Timepoints	
	1. Confirmation of diagnosis for COVID-19 infection based on RT-PCR / end of quarantine period as per standard protocol.	Every third day till 21st day.	
Secondary Outcome	Outcome	Timepoints	
	<ol style="list-style-type: none"> To compare the asymptomatic/symptomatic Covid-19 positive cases between the groups. 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 third day till 21st day.	
Target Sample Size	Total Sample Size=33000 Sample Size from India=33000 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)	24/05/2020		
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)	Not Yet Recruiting
Publication Details	None yet.
Brief Summary	The results of the study will be able to estimate the prophylactic effect of <i>Arsenicum album</i> 30C 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.