



Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 15:00:28 GMT)

CTRI Number	CTRI/2020/05/024969 [Registered on: 01/05/2020] - Trial Registered Prospectively	
Last Modified On		
Post Graduate Thesis	No	
Type of Trial	Interventional	
Type of Study	Homeopathy	
Study Design	Randomized, Parallel Group, Placebo Controlled Trial	
Public Title of Study	Homoeopathy as adjuvant in management of Covid-19 infection	
Scientific Title of Study	Effect of adjuvant homoeopathy with standard treatment protocol in management of covid-19: a randomised, open label, placebo controlled, parallel group 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	
	Name	Prof Dr Pradeep Kumar Gupta
	Designation	Principal
	Affiliation	Naiminath Homoeopathic Medical College, Hospital and Research Centre
	Address	N.H.19, Firozabad Road, Nawalpur, Etmadpur, Agra, Uttar Pradesh Agra UTTAR PRADESH 283202 India
	Phone	9765270885
	Fax	
	Email	nhmcagra@gmail.com
Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
	Name	Dr Debadatta Nayak
	Designation	Research Officer/Scientist-II
	Affiliation	CCRH
	Address	61-65, Sewa Marg, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 61-65, Sewa Marg, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 South West DELHI 110058 India
	Phone	09873404012
	Fax	
	Email	drdnayak@gmail.com
Details Contact Person (Public Query)	Details Contact Person (Public Query)	
	Name	Dr Anil Khurana
	Designation	Director General Incharge
	Affiliation	CCRH
	Address	61-65, Sewa Marg, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 61-65, Sewa Marg, Opp D Block, Institutional Area, Janakpuri, New Delhi, Delhi 110058 South West DELHI 110058 India



Phone	09911127619			
Fax				
Email	anilnaman@rediffmail.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Naininath Homoeopathic Medical College, Hospital and Research Centre			
Primary Sponsor	Primary Sponsor Details			
Name	Naininath Homoeopathic Medical College Hospital and Research Centre			
Address	N.H.19, Firozabad Road, Nawalpur, Etmadpur, Agra, Uttar Pradesh – 283202			
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
	Prof Dr Pradeep Kumar Gupta	F.H. Medical College and Hospital	Near Etmadpur, Railway over bridge, N.H -2 , Agra, Uttar Pradesh - 283201 Agra UTTAR PRADESH	9765270885 nhmcagra@gmail.com
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
	Institutional Ethics Committee-F H Medical College	Approved	20/04/2020	Yes
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 medicines will be given to this group patients as an add-on to standard treatment. Following Individualization medicines will be selected keeping in view pathological aspect of disease. Dose and potency will be according to the frequency, intensity and duration of signs and symptoms. Repetitions will vary from case to case basis considering disease state and vitality of patient. Range of potency from 30, 200, 1M etc will be used.	
	Comparator Agent	Placebo	Placebo group patients will receive identical placebo	



		(globules moistened with dispensing alcohol) as an add on to standard protocol treatment. Dose repetition will be a in similar pattern to medicine group.
Inclusion Criteria	Inclusion Criteria	
	Age From	18.00 Year(s)
	Age To	80.00 Year(s)
	Gender	Both
	Details	<ul style="list-style-type: none"> o Symptomatic RT-PCR confirmed cases of Covid-19 infection. o Both sexes o Age between 18 years to 80 years and o Willing to give signed written informed consent
Exclusion Criteria	Exclusion Criteria	
	Details	<ol style="list-style-type: none"> 1. Patients requiring ventilatory support 2. Patients with compromised immunity 3. Severe heart, lung, kidney, brain, blood diseases or other important systemic diseases 4. Subjects unable to complete the study, or not suitable for the study by researchers. 5. Women during pregnancy 6. Lactating mothers
Method of Generating Random Sequence	Computer generated randomization	
Method of Concealment	Not Applicable	
Blinding/Masking	Open Label	
Primary Outcome	Outcome	Timepoints
	Clinical outcome in terms of recovery of patient or requirement of life support (ventilator)/ death.	Ever 24 hr.
Secondary Outcome	Outcome	Timepoints
	<ul style="list-style-type: none"> i. Time to progression to critical stage ii. Time to fever clearance iii. Time to resolution of pneumonia iv. Change in severity of symptoms as per clinical syndromes associated with COVID - 19 infection. v. Time to recovery in terms of 2 negative test for Covid-19 vi. Period of hospital stay vii. Requirement of conventional medication till clinical improvement 	Ever 24 hr.
Target Sample Size	Total Sample Size=100 Sample Size from India=100 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)	10/05/2020
Date of First Enrollment (Global)	10/05/2020
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	
Brief Summary	The results of the study will be able to predict the role of add on homoeopathic treatment for management of Covid-19 infected. In the absence any known anti-viral and vaccine the positive results of this study will decrease the morality and morbidity due to this pandemic. Further the cost-effectiveness of homoeopathy will enable developing countries in controlling such deadly disease effectively.