



Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 14:39:50 GMT)

<b>CTRI Number</b>	CTRI/2020/05/025049 [Registered on: 06/05/2020] - <b>Trial Registered Prospectively</b>	
<b>Last Modified On</b>	05/05/2020	
<b>Post Graduate Thesis</b>	No	
<b>Type of Trial</b>	Interventional	
<b>Type of Study</b>	Homeopathy	
<b>Study Design</b>	Cluster Randomized Trial	
<b>Public Title of Study</b>	A CLINICAL TRIAL TO STUDY THE EFFICACY OF HOMOEOPATHIC MEDICINE IN PREVENTION AND CURE OF CORONA VIRUS DISEASE 19	
<b>Scientific Title of Study</b>	PROVING THE EFFICACY OF HOMOEOPATHIC TREATMENT IN PREVENTION AND CURE OF COVID 19	
<b>Secondary IDs if Any</b>	<b>Secondary ID</b>	<b>Identifier</b>
	NIL	NIL
<b>Details of Principal Investigator or overall Trial Coordinator (multi-center study)</b>	<b>Details of Principal Investigator</b>	
	<b>Name</b>	DR DHIRENDRA TIWARI
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<b>Details Contact Person (Scientific Query)</b>	<b>Details Contact Person (Scientific Query)</b>	
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<b>Source of Monetary or Material Support</b>	<b>Source of Monetary or Material Support</b>			
	> LATE VEDVATI DUBEY SIKSHAN SAMITI, AMBIKAPUR, CHHATTISGARH 497001 > SAI NIDAN HOMOEOPATHY CLINIC NEAR SAI MANDIR , BANARAS ROAD, AMBIKAPUR, CHHATTISGARH, 497001			
<b>Primary Sponsor</b>	<b>Primary Sponsor Details</b>			
	<b>Name</b>	SAI NIDAN HOMOEOPATHY CLINIC		
	<b>Address</b>	NEAR SAI MANDIR , BANARAS ROAD, AMBIKAPUR, CHHATTISGARH, 497001		
	<b>Type of Sponsor</b>	Private hospital/clinic		
<b>Details of Secondary Sponsor</b>	<b>Name</b>	<b>Address</b>		
	DR ASHISH DUBEY	LATE VEDVATI DUBEY SIKSHAN SAMITI, AMBIKAPUR, CHHATTISGARH 497001		
<b>Countries of Recruitment</b>	<b>List of Countries</b>			
	India			
<b>Sites of Study</b>	<b>Name of Principal Investigator</b>	<b>Name of Site</b>	<b>Site Address</b>	<b>Phone/Fax/Email</b>
	DR DHIRENDRA TIWARI	SAI NIDAN HOMOEOPATHY CLINIC	NEAR SAI MANDIR , BANARAS ROAD, AMBIKAPUR, CHHATTISGARH, 497001 Surguja CHHATTISGARH	9926190306 drdhiren16@yahoo.co.in
<b>Details of Ethics Committee</b>	<b>Name of Committee</b>	<b>Approval Status</b>	<b>Date of Approval</b>	<b>Is Independent Ethics Committee?</b>
	CG H R I INSTITUTIONAL ETHICS COMMITTEE	Approved	30/04/2020	No
<b>Regulatory Clearance Status from DCGI</b>	<b>Status</b>		<b>Date</b>	
	Not Applicable		No Date Specified	
<b>Health Condition / Problems Studied</b>	<b>Health Type</b>		<b>Condition</b>	
	Patients		Coronavirus as the cause of diseases classified elsewhere	
<b>Intervention / Comparator Agent</b>	<b>Type</b>	<b>Name</b>	<b>Details</b>	
	Intervention	ARSENIC ALBUM 30	HOMOEOPATHIC MEDICINE ARSENIC ALBUM IN POTNTISED FORM OF 30 CENTICIMAL POTENCY OD DAILY FOR 3 DAYS	
	Comparator Agent	NOT APPLICABLE	NOT APPLICABLE	
<b>Inclusion Criteria</b>	<b>Inclusion Criteria</b>			
	<b>Age From</b>	5.00 Year(s)		
	<b>Age To</b>	65.00 Year(s)		
	<b>Gender</b>	Both		
	<b>Details</b>	MALES OR FEMALES WITH A DIAGNOSIS OF COVID 19 AND MALES OR FEMALES QUARANTINE PERSON FOR COVID 19		
<b>Exclusion Criteria</b>	<b>Exclusion Criteria</b>			



	<b>Details</b>	NIL
<b>Method of Generating Random Sequence</b>	Computer generated randomization	
<b>Method of Concealment</b>	Centralized	
<b>Blinding/Masking</b>	Open Label	
<b>Primary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Primary endpoint of this trial will be measured in terms of clinically recovered cases (covid 19 negative) or death	1 MONTH
<b>Secondary Outcome</b>	<b>Outcome</b>	<b>Timepoints</b>
	Improvement in the quality of life w.r.t. activity, appetite, sleep and general condition of patient. fever clearance, changes in severity of symptoms, resolution of pneumonia	every 7 days
	Suspected cases in quarantine confirmed as negative	14 days
<b>Target Sample Size</b>	<b>Total Sample Size=100</b> <b>Sample Size from India=100</b> <b>Final Enrollment numbers achieved (Total)=Applicable only for Completed/Terminated trials</b> <b>Final Enrollment numbers achieved (India)=Applicable only for Completed/Terminated trials</b>	
<b>Phase of Trial</b>	Phase 2/ Phase 3	
<b>Date of First Enrollment (India)</b>	08/05/2020	
<b>Date of First Enrollment (Global)</b>	No Date Specified	
<b>Estimated Duration of Trial</b>	<b>Years=0</b> <b>Months=3</b> <b>Days=0</b>	
<b>Recruitment Status of Trial (Global)</b>	Not Applicable	
<b>Recruitment Status of Trial (India)</b>	Not Yet Recruiting	
<b>Publication Details</b>	NIL	
<b>Brief Summary</b>	<p>THIS STUDY IS A CLUSTER RANDOMIZED TRIAL OF HOMOEOPATHIC MEDICINE ARSENIC ALBUM 30 OD DAILY 3 DAYS IN COVID 19 POSITIVE PERSONS AND SUSPECTED QUARANTINE PERSONS THAT WILL BE CONDUCTED IN 4 CENTRES IN INDIA. THE PRIMARY OUTCOME MEASURES WILL BE EFFICACY IN CURING AND PREVENTION OF COVID19. THE SECONDARY OUTCOME WILL BE PREVENTION OF COVID19.</p>	