Clinical Trial Details (PDF Generation Date :- Fri, 25 Sep 2020 15:24:02 GMT)

CTRI Number	CTRI/2020/04/024947 [Registered on: 30/04/2020] - **Trial Registered Prospectively**
Last Modified On	30/04/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Homeopathy
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Clinical trial on effects of homeopathic medicine made from cadamba on COVID-19
Scientific Title of Study	Drug Proving & checking its effectiveness in treatment of COVID 19

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	Prashant katre
Designation	Doctor
Affiliation	Homoeo clinic
Address	dr katre house homoeo clinic civil line homoeo clinic civil line Gondiya MAHARASHTRA 441601 India
Phone	9325259285
Fax	
Email	priti.katre@gmail.com

Details Contact Person (Scientific Query)

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Name	Prashant katre
Designation	Doctor
Affiliation	Homoeo clinic
Address	dr katre house homoeo clinic civil line homoeo clinic civil line Gondiya MAHARASHTRA 441601 India
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Source of Monetary or Material Support

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> at present in basic level i have arranged raw material on my own

Primary Sponsor

Primary Sponsor Details	
Name	Dr Priti katre
Address	Homoeo clinic civil line locoshed road Gondia Maharashtra 441601
Type of Sponsor	Private hospital/clinic

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 Prashant katre	homoeo clinic	Gondia homeopathic institute surya tola Gondia Maharashtra Gondiya MAHARASHTRA	9325259285 priti.katre@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Gondia homoeopathic medical college and hospital research ethic review committee	Approved	25/04/2020	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	cadamba drug therapy	1st 3 days 6 doses in every 2 hours QID 3 days then TDS for weeks potency 200

Inclusion Criteria

Inclusion Criteria	
Age From	1.00 Day(s)
Age To	90.00 Year(s)
Gender	Both
Details	1 COVID affected individual (serologically positive) symptomatic, mild hospitalized 2 asymptomatic (serologically positive)

Exclusion Criteria

Exclusion Criteria	
Details	1.Malabsorption or inadequate oral intake 2.unexplained, chronic diarrhea, defined as more than 3 loose stool per day persisting for 2 weeks or more within the month prior to study entry. 3. Active malignancy or anticipated need for chemotherapy during the study

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Other

Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
with refrance to time scale T1-T4 -- from 5-7 weeks we expect complete recovery of patient who presented with initial symptoms. 1 patient should be asymptomatic with gental recovery (with serologically negative blood test) within 7-14 days after administration of 1st dose of medicine. 2 asymptomatic patient (serologically positive) will remain asymptomatic and should be serologically negative after 7-14 days of treatment.	with refrance to time scale T1-T4 -- from 5-8 weeks we expect complete recovery of patient who presented with initial symptoms.

Secondary Outcome

Outcome	Timepoints
with refrance to time scale T1-T5 if patient have late symptoms with initial pathological changes in vital organs we expect recovery by day 14 1 we can conclude after the study is complete.	(T1 to T5) T1- presentation before medicine intake. T2- observation for 1-3 days after drug intake. T3- 3 to 7days gradual disappearance of initial symptoms. T4- after 7 days recovery expected. T5- If associated with other secondary complaints expected recovery is by 7-14 days.

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 3
Date of First Enrollment (India)	08/05/2020
Date of First Enrollment (Global)	No Date Specified
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	nil
Brief Summary	chemical components of this drug help us to resolve • **Anti-viral** • **Anti-inflammatory** • **Anti-pyretic** • **Anti-diarrheal** • **Wound healing properties** • **Strong immuno-modulator** **Blood purifier** **also the raw material of drug resembles to that of the virus which full fills the criteria of homoeopathy that is doctrine of signature** **so i hope this drug of mine can help us fight covid 19 pandemic**