Clinical Trial Details (PDF Generation Date :- Fri, 09 Oct 2020 04:20:28 GMT)

CTRI Number	CTRI/2020/04/024846 [Registered on: 24/04/2020] - **Trial Registered Prospectively**
Last Modified On	25/06/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A Clinical Trial of Mycobacterium w in Critically Ill COVID 19 Patients
Scientific Title of Study	A clinical trial to evaluate the safety and efficacy of Mycobacterium W in critically ill patients suffering from COVID 19 infection

Secondary IDs if Any

Secondary ID	Identifier
CRSC20004, version no. 02, 10.04.2020	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Sanjay Patel
Designation	Senior Manager
Affiliation	Cadila Pharmaceuticals Limited
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Anil Avhad
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Cadila Pharmaceuticals Limited

Primary Sponsor

Primary Sponsor Details	
Name	Cadila Pharmaceuticals Limited
Address	1389, Trasad Road, Dholka, Ahmedabad - 382225, Gujarat, India.
Type of Sponsor	Pharmaceutical industry-Indian

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 Md Sabah Siddiqui	All India Institute of Medical Science, Raipur	Great Eastern Rd, AIIMS Campus, Tatibandh, Raipur, Chhattisgarh 492099 Raipur CHHATTISGARH	918518881911 dr.sabah@aiimsraipur.edu.in
Dr Sarman Singh	All India Institute of Medical Sciences, Bhopal	Saket Nagar, Bhopal Madhya Pradesh, India Bhopal MADHYA PRADESH	91-755-2672317 director@aiimsbhopal.edu.in
Dr Randeep Guleria	All India Institute of Medical Science, Delhi	A Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029 New Delhi DELHI	919810184738 randeepguleria2002@yahoo.com
Dr Inderpaul Singh Sehgal	Post Graduate Institute of Medical Education and Research	Sector 12, Chandigarh. 160012. India. Chandigarh CHANDIGARH	01722756823 inderpgi@outlook.com
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee, AIIMS, Delhi	Approved	19/05/2020	No
Institutional Ethics Committee, BHU	Approved	27/05/2020	No
Institutional Ethics Committee, PGIMER, Chandigarh	Approved	27/04/2020	No
Institutional Human	Approved	22/04/2020	No

Ethics Committee, AIIMS, Bhopal			
Institutional Human Ethics Committee, AIIMS, Raipur	Approved	11/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	15/04/2020

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere
Patients	Diseases of the respiratory system

Intervention / Comparator Agent

Type	Name	Details
Intervention	Suspension of heat killed (autoclaved)Mycobacterium w	0.3 ml (0.1 ml x 3 Inj.) of Mw intra-dermal for 3 consecutive days with Standard therapy of COVID-19
Comparator Agent	Placebo	0.3 ml (0.1 ml x 3 Inj.) of Placebo intra-dermal for 3 consecutive days with Standard therapy of COVID-19

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Critically ill patients infected with COVID-19 (clinical/confirmed) 2. Patient aged 18 years or more of either gender 3. Illness of any duration with respiratory rate ?25 breaths/minute, and at least one of the following: - Radiographic infiltrates by imaging (chest x-ray, CT scan, etc.), or - SpO2 ?94% on room air, or - Requiring mechanical ventilation and/or supplemental oxygen 4. Female patients of childbearing potential must have a negative pregnancy test within 14 days prior to first dose of study medication. 5. Subject (or legally authorized representative) provides written informed consent prior to initiation of any study procedure.

Exclusion Criteria

Exclusion Criteria	
Details	1. Pregnant or nursing female. 2. Patients with history of allergy, hypersensitivity, or any serious reaction to study medication 3. Patients with a concomitant medical condition, whose participation, in the opinion of the investigator, may create an unacceptable additional risk. 4. Patient previously enrolled into this study. 5. Patient participating or having participated in a clinical trial with another investigational drug within the last 28 days except for investigational drugs against cancer, leukemia or HIV. 6. Patients with a life expectancy judged to be less than five days 7. ALT/AST > 5 times the upper limit of normal 8. Stage 4 severe chronic kidney disease or requiring dialysis (i.e. eGFR 9. Patients not likely to complete the trial as per judgment of the investigator.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized

Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
To evaluate the efficacy of Mw by measuring the improvement in organ dysfunction (or occurrence of new organ dysfunction) based on Change in Sequential Organ Failure Assessment (SOFA) score and Ordinal scale.	From baseline to day 3, 7, 14, 21 and 28 and day of transfer from ICU, if earlier than 28 days.

Secondary Outcome

Outcome	Timepoints
To evaluate all-cause mortality till day 28	All-cause mortality till day 28
To evaluate the safety/tolerability by determining the incidence of adverse events in the Mw	Any AE / SAE or event of clinical significance observed during the study.

Target Sample Size	**Total Sample Size=**40 **Sample Size from India=**40 **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	N/A
Date of First Enrollment (India)	30/04/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	
Brief Summary	Eligible patients will be enrolled after due consent and will be randomized in balance to receive either test drug (along with the standard of care) or placebo (along with the standard of care). The enrolled patients will be monitored for any adverse events (AEs) or serious adverse events (SAEs) throughout the study period. All patients will continue to receive standard therapy till considered requisite by the treating physician. In addition to the standard care for COVID-19, patients randomized to test arm will receive single daily dose of 0.3 ml of Mw, intradermal, for 3 consecutive days while patients randomized to control arm will receive single daily dose of 0.3 ml of water for injection, intradermal, for 3 consecutive days. Study duration for each patient will be 28 days.