Clinical Trial Details (PDF Generation Date :- Fri, 09 Oct 2020 04:28:11 GMT)

CTRI Number	CTRI/2020/05/025271 [Registered on: 20/05/2020] - **Trial Registered Prospectively**
Last Modified On	28/09/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Clinical Trial of Mycobacterium w in COVID-19 Positive Patients, Hospitalized But Not Critically Ill
Scientific Title of Study	A Randomized, Double-blind, Two arm, controlled clinical trial to compare the Efficacy and Safety of Mycobacterium w (Mw) administered along with Standard of care versus Placebo administered along with Standard of care, in adult, COVID 19 positive patients hospitalized but not critically ill.

Secondary IDs if Any

Secondary ID	Identifier
CRSC20006, version no. 02, 15.04.2020	Protocol Number

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

Details of Principal Investigator	
Name	Dr Sanjay Patel
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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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 Anant Mohan	All India Institute of Medical Science, Delhi	A Sri Aurobindo Marg, Ansari Nagar, Ansari Nagar East, New Delhi, Delhi 110029. New Delhi DELHI	911126588700 anantmohan88@gmail.com
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee,	Approved	26/05/2020	No

AIIMS, Delhi			
Institutional Ethics Committee, AIIMS, Raipur	Approved	22/06/2020	No
Institutional Ethics Committee, JJ Group of hospital	Approved	30/07/2020	No
Institutional Ethics Committee, King Georges Medical University	Approved	14/09/2020	No
Institutional Ethics Committee, PGIMER, Chandigarh	Approved	16/06/2020	No
Institutional Human Ethics Committee, AIIMS, Bhopal	Approved	17/05/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	22/04/2020

Health Condition / Problems Studied

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

Intervention / Comparator Agent

Type	Name	Details
Intervention	Suspension of heat killed (autoclaved)Mycobacterium w	0.3 ml (0.1ml x 3 Injection) of intradermal Mw for 3 consecutive days with Standard therapy of COVID-19
Comparator Agent	Placebo	0.3 ml (0.1 ml x 3 Inj.) of intradermal Placebo 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. COVID-19 positive patients with ordinal scale score of 3 with comorbid illness including diabetes mellitus, hypertension, chronic lung disease, immunocompromised status, active malignancy, chronic kidney disease, chronic liver disease, obesity (BMI>25Kg/m2), or subjects who have doubling of CRP compared to baseline or have Neutrophil-to-Lymphocyte Ratio ?3.5. 2. Patients of either gender, age ? 18 years at the time of enrollment. 3. Female patients who are currently using reliable methods of contraception (barrier methods and intrauterine contraceptive device), with a negative urine pregnancy test during screening and agree to informed compliance of contraceptive method until at least 3 months post-dosing. 4. The patients must be able and willing to comply with the study protocol, available and willing to complete all the study assessments and must have signed an Informed Consent Form.

Exclusion Criteria

Exclusion Criteria	
Details	1. Patient with ordinal scale of ?4 at the time of hospital admission and randomization. 2. Pregnant and / or lactating female patients.

	3. A family history of congenital or hereditary immunodeficiency. 4. Any disease condition requiring ICU admission. 5. History of dialysis, silicosis, solid organ transplantation such as renal or cardiac transplants, and disorders of the heart, or nervous system, or other metabolic inflammatory conditions, psychiatric, occupational problems that make it unlikely that the patients will comply with the protocol as determined by the investigator. 6. History of administration of any immunoglobulins, any immunotherapy (antineoplastic chemotherapy, radiation therapy, immunosuppressants to induce tolerance to transplants, and corticosteroids use) and/or any blood products within the 3 months preceding study dosing, or planned future administrations during the study period. 7. History of allergic reactions or anaphylaxis to Mw or its component. 8. Presence of any severe systemic/autoimmune disorders as determined by medical history and/or physical examination at the time of screening, which in the judgment of the Investigator would compromise the patient's health or is likely to result in nonconformance to the protocol or a patient's ability to give written informed consent.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Number of patients with increased disease severity	From baseline to at any time during the study till 28 days post first dosing.

Secondary Outcome

Outcome	Timepoints
Incidence of adverse events and serious adverse events (Safety)	Till day 28
Number of COVID-19 patients discharged from hospital	From baseline to at any time during the study till 28 days post first dosing.
Number of COVID-19 patients transfer to ICU	From baseline to at any time during the study till 28 days post first dosing.
Number of COVID-19 patients with reduction in disease severity by 1 ordinal scale	From baseline to at any time during the study till 28 days post first dosing.
Number of of symptom free patients	From baseline to at any time during the study till 28 days post first dosing.

Target Sample Size	**Total Sample Size=**480 **Sample Size from India=**480 **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)	31/05/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of	Open to Recruitment

Trial (India)	
Publication Details	
Brief Summary	In a randomized, double blind, two arms, placebo controlled, clinical trial, total 480 hospitalized adult eligible patients will be randomized to study to evaluate the the safety and efficacy of Mycobacterium w versus placebo for preventing the progression of COVID-19 disease and for reduction in transfer to ICU in COVID-19 infected patients admitted to the hospital. Patients will be continued with the standard of care. Daily clinical evaluation of patient will be performed till discharge from hospital or till ICU admission. Study duration for each patient will be approximately up to 28 days, or discharge from hospital or transfer to ICU, whichever is earlier.