Clinical Trial Details (PDF Generation Date :- Fri, 09 Oct 2020 04:23:19 GMT)

CTRI Number	CTRI/2020/05/025277 [Registered on: 21/05/2020] - **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 Preventing COVID-19 in Subjects at Risk of Getting Infected With COVID-19
Scientific Title of Study	A Randomized, Double-blind, Two arm, Placebo Controlled Clinical Trial to Evaluate the Efficacy and Safety of Mycobacterium w in preventing COVID-19 in subjects at risk of getting infected with COVID-19.

Secondary IDs if Any

Secondary ID	Identifier
CRSC20005, 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)

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

Source of Monetary or Material Support
> Cadila Pharmaceuticals Limited 1389, Trasad Road, Dholka, Ahmedabad – 382225, Gujarat, India.

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 Sarman Singh	All India Institute of Medical Sciences, Bhopal	Saket Nagar, Bhopal Madhya Pradesh, India Bhopal Bhopal MADHYA PRADESH	91-755-2672317 director@aiimsbhopal.edu.in
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		CHANDIGARH	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee, AIIMS, Delhi	Approved	29/05/2020	No
Institutional Ethics Committee, AIIMS, Raipur	Approved	11/05/2020	No
Institutional Ethics Committee, Apollo, Hyderabad	Approved	30/05/2020	No
Institutional Ethics Committee, JJ Group of hospital	Approved	30/07/2020	No
Institutional Ethics Committee, King Georges Medical University	Approved	02/09/2020	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	0.2 ml (0.1 ml x 2 Inj.) of intradermal Mw on day 0 and 0.1 ml of intradermal Mw on day 15
Comparator Agent	Placebo	0.2 ml (0.1 ml x 2 Inj.) of intradermal Placebo on day 0 and 0.1 ml of intradermal Placebo on day 15

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1.Healthy subjects with recent history of close contact with COVID-19 patients. 2.Subjects with SARS Cov 2 negative test (ICMR approved test kit) at screening visit. 3.Subject of either gender, age ? 18 years at the time of enrollment. 4.Female subject 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. 5.The subject 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.Any febrile illness with oral temperature > 100°F within 3 days prior to randomization. 2.Subject with past history of COVID-19 infection. 3.Pregnant and / or lactating female subjects. 4.Presence of any illness requiring hospital referral. 5.Any confirmed or suspected immune-deficient condition based on medical history and physical examination and a family history of congenital or hereditary immunodeficiency or Individuals on immunosuppressant's as Azathioprine, Cyclosporine, Mycophenolate etc. 6.History of allergic reactions or anaphylaxis to Mw or its component.

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

Primary Outcome

Outcome	Timepoints
No. of subjects acquiring COVID-19 infection	From first dosing till 8 week post first dosing.

Secondary Outcome

Outcome	Timepoints
Incidence of Adverse Event and Serious Adverse Event (safety and tolerability)	Till 8 weeks
Development of Upper Respiratory Tract Infection (URTI) symptoms.	From first dosing till 8 week post first dosing
Development of severe COVID-19 infection based on ordinal scale	From first dosing till 8 week post first dosing

Target Sample Size	**Total Sample Size=**4000 **Sample Size from India=**4000 **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=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	
Brief Summary	Approximately 4000 eligible subjects who are at risk of getting infected with COVID-19 will be enrolled in to this randomized, blinded, two arms, placebo controlled, clinical trial to evaluate the safety and efficacy of Mycobacterium w in preventing COVID-19 infection. Subjects will be randomized in 1:1 ratio to receive either Mw or placebo. Study duration for each subject will be of 8 weeks.