Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 14:24:06 GMT)

CTRI Number	CTRI/2021/03/032051 [Registered on: 16/03/2021] - **Trial Registered Prospectively**
Last Modified On	30/03/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Trial to evaluate 3mg dose of Covid Vaccine of Cadila healthcare Limited
Scientific Title of Study	A prospective, randomized, phase I/II clinical study to evaluate the safety and immunogenicity of 3mg dose of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects

Secondary IDs if Any

Secondary ID	Identifier
Project No. 21-01; Version No. 01 Dated 17-02-2021	Protocol Number

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

Details of Principal Investigator	
Name	Dr Ravindra Mittal
Designation	Medical Advisor & Head - Regulatory Affairs
Affiliation	Cadila Healthcare Limited
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Jayesh Sanmukhani
Designation	Deputy General Manager - New Product Development
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
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Phone	7600012192
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Email	jayeshsanmukhani@zyduscadila.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Cadila Healthcare Limited

Primary Sponsor

Primary Sponsor Details	
Name	Cadila Healthcare Limited
Address	Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad
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 Jinen Mukeshbhai Shah	Aartham Multi Super Speciality Hospital	Clinical Research Room - Basement 2; Aartham Hospital, Opp. Polytechnic, Nr. Panjarapole cross road, Ambawadi Ahmadabad GUJARAT	9724440891 jinenshah@gmail.com
Dr Abhishek Pande	Axon Multispeciality Hospital Rukhmini Complex	Research Room, Axon hospital, Hingna Rd, near Mascott Honda, Bansi Nagar Nagpur MAHARASHTRA	8793653698 dr_abhishekpande@yahoo.com
Dr Chandra Prakash Suthar	Dana Shivam Heart & Superspeciality Hospital	Clinical Research Room, Basement, Dana Shivam hospital, Plot No:2, Opp. Times Square, Sector 2, Vijay Bari, Vidyadhar Nagar Jaipur RAJASTHAN	9413861322 danashivam.cr@gmail.com
Dr Amit Bhate	Jeevan Rekha Hospital	Clinical Research Department, Second Floor, Jeevan Rekha Hospital, Dr. B.R. Ambedkar Road Opp Civil Hospital Belagavi (Belgaum) Belgaum KARNATAKA	9695237796 dr.amitsureshbhate@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
IEC Maharaja Agrasen Hospital	Approved	23/02/2021	No
Institutional Ethics Committee Jeevan Rekha Hospital	Approved	22/03/2021	No

Institutional Ethics Committee of Vidharbha Institute of Medical Sciences	Approved	27/02/2021	No
Sangini Hospital Ethics Committee	Approved	25/02/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	15/03/2021

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy Volunteers

Intervention / Comparator Agent

Type	Name	Details
Intervention	Novel Corona Virus-2019-nCov vaccine of M/s. Cadila Healthcare Limited (ZyCoVD)	3 mg dose (0.1ml dose at three sites) to be given twice at day 0 and 28
Comparator Agent	Placebo	0.1ml dose at three sites to be given twice at day 0 and 28

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	60.00 Year(s)
Gender	Both
Details	1. Healthy subject of either gender 18 to 60 years of age 2. Informed consent from the subjects (Audio video recording in case of vulnerable subject) 3. Adult subjects literate enough to fill the diary card 4. Females of childbearing potential, must agree to use one of the approved contraception methods (double barrier methods, oral or injectable hormonal contraceptives or surgical sterilization), from screening until completion of the follow-up visit and males who agree to use contraception

Exclusion Criteria

Exclusion Criteria	
Details	1. Febrile illness (temperature ? 38°C or 100.4°F) or any acute illness or infection within 4 weeks of enrolment 2. History or laboratory evidence of confirmed SARS-CoV-2 positive 3. History of contact with a confirmed active SARS-CoV-2 positive patient within 14 days 4. Subjects positive for antibodies against SARS-CoV-2 on antibody detection test / RTPCR positive at the time of screening 5. History of SARS/ MERS infection 6. Previous participation in any clinical trial of a SARS-CoV-2 candidate vaccine 7. Past history of hypersensitivity reaction or any serious adverse event after any vaccination 8. Subjects with thrombocytopenia or any coagulation disorder, or subjects on anticoagulation therapy 9. Subjects with confirmed or suspected immunosuppressive or immunodeficiency disorder; or subjects on any immunosuppressive or immunostimulant therapy 10. Clinically significant systemic disorder such as cardiovascular, respiratory, neurologic, gastrointestinal, hepatic, renal, endocrine, haematological, psychiatric or immunological disorder 11. Subjects administered blood, blood containing products or immunoglobulins within the last 3 months or planned administration during the study 12. Any other vaccine administration within the last 30 days or planned to be administered during the study period 13. Pregnant and lactating women & female subjects not using

	acceptable contraceptive measures (double barrier methods, oral or injectable hormonal contraceptives or surgical sterilization) 14. Participation in another clinical trial in the past 3 months 15. History of drug / alcohol abuse

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
Adverse events (solicited, unsolicited and SAEs) reported during the study in the two groups Seroconversion rate based on IgG antibodies against S1 antigen (by ELISA) at Day 56.	Day 56

Secondary Outcome

Outcome	Timepoints
Seroconversion rate based on of IgG antibodies against S1 antigen (by ELISA)	Day 28 and 42
Geometric Mean Titre and Geometric Mean Fold Rise	Day 28, 42 and 56
Neutralizing antibody assay	Day 42 and 56

Target Sample Size	**Total Sample Size=**150 **Sample Size from India=**150 **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 1/ Phase 2
Date of First Enrollment (India)	19/03/2021
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	NA
Brief Summary	The current study is being planned as a proof of concept study to evaluate the effect of 2 doses of 3mg given by Pharmajet at interval of 28 days. healthy subjects will be screened as per inclusion and exclusion criteria and will be randomized in 2:1 ratio to receive either the vaccine or placebo. Randomized subjects will be given two doses of vaccine / placebo at an interval of 28 days. Each dose of vaccine / placebo comprises of 3mg (0.3 ml) Novel Corona Virus-2019-nCov vaccine / placebo. The vaccine / placebo will be given as 3 shots of 0.1ml each via intradermal route using Pharmajet Tropis device at three different sites on the upper arm. Subjects will be followed for 28 days after last dose of vaccine. Blood samples will be taken at Day 0, 28, 42 and 56 for immunogenicity analysis.