



Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 09:49:18 GMT)

CTRI Number	CTRI/2021/01/030416 [Registered on: 12/01/2021] - Trial Registered Prospectively		
Last Modified On	30/08/2022		
Post Graduate Thesis	No		
Type of Trial	Interventional		
Type of Study	Vaccine		
Study Design	Other		
Public Title of Study	Novel Corona Virus-2019-nCov vaccine by intradermal route in healthy subjects.		
Scientific Title of Study	A phase III, randomized, multi-centre, double blind, placebo controlled, study to evaluate efficacy, safety and immunogenicity of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited.		
Secondary IDs if Any	Secondary ID	Identifier	
	NCOV.20.002,Version 03, dated 08 January 2021	Protocol Number	
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	Details of Principal Investigator		
	Name	Dr Ravindra Mittal	
	Designation	Senior Vice President	
	Affiliation	Cadila Healthcare Limited	
	Address	Zydus Corporate Park, Scheme No. 63, Survey No. 536, Nr. Vaishnodevi Circle, S.G. Highway. Ahmadabad GUJARAT 382481 India	
	Phone	07948040000	
	Fax		
	Email	r.mittal@zyduscadila.com	
	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
		Name	Dr Kevinkumar Kansagra
Designation		General Manager	
Affiliation		Cadila Healthcare Limited	
Address		Zydus Research Center, Survey No. 396/403, Sarkhej-Bavla National Highway No.8A Moraiya, Ahmadabad GUJARAT 382213 India	
Phone		02717665555	
Fax			
Email		kevinkumarkansagra@zyduscadila.com	
Details Contact Person (Public Query)	Details Contact Person (Public Query)		
	Name	Dr Ravindra Mittal	
	Designation	Senior Vice President	
	Affiliation	Cadila Healthcare Limited	
	Address	Zydus Corporate Park, Scheme No. 63, Survey No. 536, Nr. Vaishnodevi Circle, S.G. Highway. Ahmadabad GUJARAT 382213 India	



Phone	02717665555			
Fax				
Email	r.mittal@zyduscadila.com			
Source of Monetary or Material Support	Source of Monetary or Material Support			
	> Cadila Healthcare Limited, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Near Vaishnodevi Circle, S-G Highway, Ahmedabad			
Primary Sponsor	Primary Sponsor Details			
	Name	Cadila Healthcare Ltd		
	Address	Zydus Corporate Park, 3rd Floor B Wing (NPD), Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Near Vaishnodevi Circle, S-G Highway, Ahmedabad – 382 481 ,		
	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 Deepak Langade	DR. D.Y.Patil Medical College and Hospital	5th Floor Department of Pharmacology, College building, DR. D.Y.Patil Medical College and Hospital, Nerul Sector 5 Navi Mumbai- 400706. Mumbai MAHARASHTRA	2227735999 deepak.langade@dypatil.edu
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	Dr Pankaj Bharadwaj	All India Institute of Medical Sciences	All India Institute of Medical Sciences, Jodhpur-342005, Rajasthan India Jodhpur RAJASTHAN	2912740741 pankajbhardwajdr@gmail.com
	Dr Vipul Khandelwal	Apex Hospital Pvt. Ltd	SP 4& 6 MIA Malviya Nagar near apex circle, Jaipur-302017 Jaipur RAJASTHAN	0141-2751871 dr.vipul@yahoo.co.in
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Dr Kalpesh Talati	Zydus Hospitals and Healthcare Research Pvt Ltd	Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad, Gujarat 380054 Ahmadabad GUJARAT	9824014187 kalpeshtalati@zydushospitals.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
"Apollo Hospital Institutional Ethics Committee- Clinical, 154/11, opp.IIM Bannerghatta Road Bengaluru, Bengaluru	Approved	03/02/2021	No



(Bangalore) Urban Karnataka-560076 "			
"Clinical Research Ethics Committee Medica Superspecialty Hospital ,127, Mukundapur E.M.Bypass Kolkata (India) - 700099 India"	Approved	23/02/2021	No
"Ethics Committee, N.R.S Medical College 138, Acharya Jagadish Chandra Bose Road, Sealdah, Kolkata, 700014, West Bengal, India"	Approved	22/02/2021	No
"Ethics Committee,N.S.C.B.C. Research Institue, 3081, Nayabad, New Garia, Kolkata 700094"	Approved	01/02/2021	No
"IEC Columbia Asia Hospital Mysore IEC CAH columbia Asia Hospitar Mysore ,No. 85-86, Bangarore Mysore Ring Road Junction, Bannimantapa A Layout, Siddiqui Nagar, Mysuru-570015"	Approved	30/01/2021	No
"Instituional Ethics Committee of Vidharba Institute of Medical Sciences, Mohan Nagar, LIC Square, Kamptee Road, Nagpur, Maharashtra 440001 "	Approved	21/01/2021	No
"Institutional Ethics Committee Guru Teg Bahadur Hospital , Dilshad Garden, Delhi 110095 "	Approved	13/02/2021	No
"INSTITUTIONAL ETHICS COMMITTEE Kurnool Medical College/Government General Hospital Budhawarpet, Kurnool Andhra Pradesh - 518002 India"	Approved	03/02/2021	No
"Institutional Ethics Committee, Dr. Vasanttrao Pawar Medical College, Hospital and Research Centre, Maharashtra - 422003, India "	Approved	18/02/2021	No



"Institutional Ethics Committee, GMERS Medical College and Civil Hospital Sola, Department of Pharmacy, 4th floor college building, Nr. Gujarat High Court, S. G. Highway, Sola, Ahmedabad 380061, Gujarat, India "	Approved	12/02/2021	No
"Manavata Clinical Research Institute Ethics Committee Opposite Mahamarg Bus Stand, Mumbai Naka, Nashik – 422004 Maharashtra, India "	Approved	19/01/2021	No
"Shree Institutional Ethics Committee Dhadiwal Hospital Research department. 4th floor, Trambakeshwar Rd, Opp. New, CBS, Matoshree Nagar, Nashik, Maharashtra 422002, India."	Approved	23/01/2021	No
AMAI Trust ACE Hospital IEC, 8/4/1, Yashwant apt, Shop No 7, Lane No 4, Karve Nagar, Pune-411052, Maharashtra, India	Approved	08/02/2021	No
Ashirwad Ethics Committee, Maratha Section, Near Jijamata Udyan, Ulhasnagar, Maharashtra 421004	Approved	22/01/2021	No
BAPS Pramukh Swami Hospital Ethics Committee, BAPS Pramukh Swami Hospital, Adajan Cross Road. Adajan. Surat-395009	Approved	11/01/2021	No
Ethics Committee - Dr. D Y Patil Vidyapeeth, Sant Tukaram Nagar, Pimpri, Pune - 411018, Maharashtra, India.	Approved	24/02/2021	No
Ethics Committee Baramati Hospital Pvt. Ltd., Baramati Hospital Pvt. Ltd., Behind Kavivarya Moropant Natyamandir, Ring Road, Baramati 413102	Approved	21/05/2021	No
Ethics Committee	Approved	31/01/2021	No



Downtown Hospital, Dispur, G S Road, Guwahati-781006			
Ethics committee of Pulse Multispeciality Hospital, Pulse Multispeciality Hospital, Sr. No. 51/7/B/1, Vishwa Arcade Bombay Banglore Highway, Narhe, Pune 411041, Maharashtra	Approved	25/03/2021	No
Ethics Committee of SMS Medical College & Attached Hospital, Office of Ethics Committee, Second Floor, New Administration Block, SMS Medical College, JLN Marg, Jaipur-302004, Rajasthan	Approved	06/02/2021	No
Ethics Committee Unique Hospital- Multispecialty & Research Institute, Opp. Kiran Motor, Nr. Canal, Civil Hospital Char Rasta- Sosyo Circle Lane, Off Ring Road, Surat- 395002, Gujarat, India	Approved	21/01/2021	No
Ethics Committee, GSVM Medical College, Room No 125, First Floor, GSVM Medical College, Swaroop Nagar, Kanpur-208002	Approved	03/02/2021	No
Ethics Committee, N.S.B.C Research Institute, 3081, Nayabad, New Garia, Kolkata-700094	Approved	01/02/2021	No
Ethics Committee, Sanjeevani cancer Hospital, Sanjeevani CBCC USA Cancer Hospital in front of Jain Mandir, Dawada Colony Pachpedi Naka, Raipur-492001	Approved	25/01/2021	No
Ethics Committee, St. Theresas Hospital, Sanathnagar, Hyderabad-500018, Telangana, India	Approved	05/02/2021	No
IEC Maharaja Agrasen Hospital, Central Spine,	Approved	10/02/2021	No



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Instituional Ethics Committee, Ajanta Research Centre, Ajanta Hospital & IVF Centre, 765, ABC Complex, Kanpur Road, Alambagh, Lucknow-226005	Approved	24/01/2021	No
Instituional Ethics Committee, Atharva Multispeciality Hospital & Research Centre, H-4/Comm-2, construction Div-21, UP Avas Vikas Parishad, Sector E, Lucknow-226003	Approved	24/01/2021	No
Instituional Ethics Committee, Jeevan Rekha Hospital, Dr. B R Ambedkar Road Belgavi-590002	Approved	23/01/2021	No
Instituional Ethics Committee, Sri Siddharta Medical College and Research Centre, B.H Road, Agalkote, Tumkur, Karnataka-572107	Approved	30/01/2021	No
Instituional Ethics Committee,GGMC Mumbai, Grant Government Medical College, J.J Road, J.J Hospital Compund, Mumbai Central, Mumbai, Mumbai City, Maharashtra, Mumbai-400008.	Approved	10/02/2021	No
Institutional Ethics Committee Apex Hospital Pvt. Ltd, Sp 4 & 6 MIA Malviya Nagar, near apex circle, Jaipur-302017	Approved	21/01/2021	No
Institutional Ethics Committee Bharati Vidyapeeth Deemed University, Institutional Ethics Committee Office, 4th floor, Bharati Hospital and Research Centre, Pune-Satara Road, Dhankawadi, Pune - 411043,	Approved	25/03/2021	No



Maharashtra, India.			
Institutional Ethics Committee Felix Hospital, Sector 137, Noida, Uttar Pradesh - 201305	Approved	25/01/2021	No
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Institutional Ethics Committee ICH, Institute of Child Health, 11, Dr. Biresb Guha Street Kolkata Kolkata West Bengal - 700017 India	Approved	07/06/2021	No
Institutional Ethics Committee, DR. D.Y.Patil Medical College, Sector 5, Nerul, Navi Mumbai- 400706.	Approved	08/02/2021	No
Institutional Ethics Committee, KLE University, KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi, (Belgaum), Karnataka - 590010, India	Approved	24/02/2021	No
Institutional Ethics Committee, Osmania Medical College, Koti, Hyderabad, Telangana	Approved	22/06/2021	No
Institutional Ethics Committee-Clinical Studies, Apollo Hospitals, No. 21, Grems Lane, Off. Grems Road, Thousands Light, Chennai, Tamil Nadu 600006	Approved	05/03/2021	No
Institutional Ethis Committee for sehgal Nursing Home, A6, Panchwati, opp Azadpur New Subzi Mandi, Delhi-110033	Approved	25/01/2021	No
Institutional Ethis Committee for sehgal Nursing Home, A6,	Approved	25/01/2021	No



Panchwati, opp Azadpur New Subzi Mandi, Delhi-110033			
Institutional Ethic Committee for sehgal Nursing Home, A6, Panchwati, opp Azadpur New Subzi Mandi, Delhi-110033	Approved	25/01/2021	No
INSTITUTIONAL HUMAN ETHICS COMMITTEE, All India Institute of Medical Sciences, Basni Jodhpur Jodhpur Rajasthan - 342005 India	Approved	03/02/2021	No
Institutional Ethics Committee, Jawahar Lal Nehru Medical College, Kala Bagh, Ajmer-305001, Rajasthan	Approved	18/02/2021	No
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Malla Reddy Medical College for women Ethics Committee, Suraram X Road, Jeedimetla, Suraram, Hyderabad, Telangana, 500055	Approved	08/02/2021	No
Marudhar Hospital Ethics Committee Marudhar Hospital A-93-99, Singh Bhoomi Khatipura Road Jaipur Jaipur Rajasthan - 302012 India	Approved	17/01/2021	No
Marudhar Hospital Ethics Committee Marudhar Hospital A-93-99, Singh Bhoomi Khatipura Road Jaipur Jaipur Rajasthan - 302012 India	Approved	17/01/2021	No
Marwari Hospitals, Sati Joymati Road Athgaon Guwahati Kamrup, Metropolitan Assam - 781008 India	Approved	29/01/2021	No



Naryana Health Medical ethics committee, 258/A Boomsandra Industrial Area, Hosur Road Anekal Taluk Bangalore 560099	Approved	08/03/2021	No
NSH Ethics Committee, NH-Narayana Superspeciality Hospital, 120/1, Andul Road, Howrah-711103, West Bengal, India.	Approved	15/02/2021	No
Parth Institutional Ethics Committee, Parth Orthopedic & Surgical Hospital, E408, Fourth Floor Galaxy Arcade, Near Galaxy Cinema, Naroda, Ahmedabad, Gujarat 382330, India.	Approved	01/07/2021	No
Pranav Diabetes Center Ethics Committee, 57/1, Nanda Complex Rammurthyagar, Mainroad, banaswadi, Bangalore, Bengaluru(Bangalore) Urban, Karnataka-5460043	Approved	25/01/2021	No
Supre Hospital Ethics Committee, Opp Adhar Ashram, Near Runghta School, Gharpure, Ashok Stambh, Nashik-422002	Approved	23/01/2021	No
Thangam Hospital-Institutional Ethics Committee(TH-IEC), 54, Dr. Sankaran Road, Namakkal-637001, Tamilnadu, India	Approved	25/01/2021	No
Vedanta Hospital Institutional Ethics Committee, Vedanta Hospital ,Beside Vasavi Cloth Market,Mangalagiri Road Guntur (India) - 522001 India	Approved	03/02/2021	No
Vrajesh Hospital Institutional Review Board, opp Rajpath Club, Cargo Motors Lane, S.G Road, 117 Boadakdev, Ahmedabad- 380015	Approved	29/01/2021	No
Zydus Hospital Ethics	Approved	09/01/2021	No



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Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	11/01/2021

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	NA

Intervention / Comparator Agent

Type	Name	Details
Intervention	Novel Corona Virus-2019-nCov Vaccine	(1)Dose:-0.2 ml (0.1ml in eacharms) with Pharmacet (2)Site of administration:- Upper Arm (3)Frequency:-single time at day 0 day 28 and day 56. (4)Route:-Intradermal
Comparator Agent	Placebo	1)Dose:-0.2 ml (0.1ml in eacharms) with Pharmacet (2)Site of administration:- Upper Arm (3)Frequency:-single time at day 0 day 28 and day 56. (4)Route:-Intradermal

Inclusion Criteria

Inclusion Criteria	
Age From	12.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1.Healthy subject of either gender ?12 years of age. 2. Agrees not to take any COVID-19 licensed vaccination for the entire duration of the study. 3. Ability to provide informed consent from the adult subjects or from the parents of paediatric subjects. Additionally, assent from paediatric subjects (Audio video recording in case of vulnerable subject). 4. Adult subjects or parents of paediatric subjects literate enough to fill the diary card. 5. Subjects with good health or with stable medical condition for chronic disease. (Stable condition is defined as there is no change in the medication or dose of medication or severity of disease from last 3 months before enrolment.) 6. 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 will agree to use contraception. 7. Willing to allow storage and future use of biological samples for future research.

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. Laboratory confirmed SARS-CoV-2 positive. 3. History of contact with a confirmed active SARS-CoV-2 positive patient within 14 days. 4. History of SARS/ MERS infection. 5. Previous participation in any clinical trial of a SARS-CoV-2 candidate vaccine.



	<p>6. Past history of hypersensitivity reaction or any serious adverse event after any vaccination.</p> <p>7. Past history of thrombocytopenia or any coagulation disorder, or subjects on anticoagulation therapy.</p> <p>8. Subjects with confirmed immunosuppressive or immunodeficiency disorder; or subjects on any immunosuppressive or immunostimulant therapy.</p> <p>9. Clinically significant systemic disorder such as cardiovascular, respiratory, neurologic, gastrointestinal, hepatic, renal, endocrine, haematological, psychiatric or immunological disorder.</p> <p>10. Subjects administered blood, blood containing products or immunoglobulins within the last 3 months or planned administration during the study.</p> <p>11. Any other vaccine administration within the last 30 days or planned to be administered during the study period.</p> <p>12. Pregnant and lactating women.</p> <p>13. Participation in another clinical trial in the past 3 months.</p> <p>14. History of drug / alcohol abuse.</p>
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Method of Generating Random Sequence Computer generated randomization

Method of Concealment Centralized

Blinding/Masking Participant, Investigator, Outcome Assessor and Data-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
To demonstrate the efficacy of ZyCoV-D in the prevention of virologically confirmed symptomatic COVID-19 cases as compared to placebo.	Day 84 to Day 364

Secondary Outcome

Outcome	Timepoints
To demonstrate the efficacy of a ZyCoV-D in the prevention of virologically confirmed severe COVID-19 cases as compared to placebo	Day 84, Day 186, Day 252, Day 364
To demonstrate the efficacy of a ZyCoV-D in the prevention of virologically confirmed moderate COVID-19 cases as compared to placebo.	Day 84, Day 186, Day 252, Day 364
To demonstrate the efficacy of a ZyCoV-D in the prevention of virologically confirmed mild COVID-19 cases as compared to placebo.	Day 84, Day 186, Day 252, Day 364
To demonstrate the efficacy of a ZyCoV-D in the prevention of virologically confirmed asymptomatic COVID-19 cases as compared to placebo.	Day 84, Day 186, Day 252, Day 364
To demonstrate the efficacy of a ZyCoV-D in the prevention of virologically confirmed COVID-19 death as compared to placebo.	Day 84, Day 186, Day 252, Day 364
To evaluate the immunogenicity by neutralizing antibody (nAb) assay in subset of population.	Day 0, Day 56, Day 84, Day 186, Day 252, Day 364
To evaluate persistence of immunogenicity after first dose of ZyCoV-D.	Day 56, Day 84, Day 168, Day 252 and Day 364
To evaluate the Lot-to-Lot consistency based on	At Day 84



	the IgG titer of the three consecutive lots used in the study.	
	To evaluate safety and tolerability of ZyCoV-D.	Day 0 to Day 364
Target Sample Size	Total Sample Size=28216 Sample Size from India=28216 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)	16/01/2021	
Date of First Enrollment (Global)	No Date Specified	
Estimated Duration of Trial	Years=1 Months=8 Days=0	
Recruitment Status of Trial (Global)	Not Applicable	
Recruitment Status of Trial (India)	Closed to Recruitment of Participants	
Publication Details	NIL	
Brief Summary	<p>Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first reported in January, 2020. The virus is highly transmissible between humans and has spread rapidly, causing the COVID-19 pandemic. Patients infected with SARS-CoV-2, especially older patients and those with pre-existing respiratory or cardiovascular conditions are at greater risk for severe complications, including severe pneumonia, acute respiratory distress syndrome, multiple organ failure, and in some cases, death. In the absence of effective prevention measures, current management to control the epidemic is the enforcement of quarantine, isolation, and physical distancing. Effective vaccines against COVID-19 are urgently needed to reduce the enormous burden of mortality and morbidity associated with SARS-CoV-2 infection.</p>	