

## Clinical Trial Details (PDF Generation Date :- Tue, 24 May 2022 07:31:14 GMT)

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| **CTRI Number** | CTRI/2020/07/026352 [Registered on: 04/07/2020] - **Trial Registered Prospectively** |
| **Last Modified On** | 08/11/2020 |
| **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 prospective, randomized, adaptive, phase I/II clinical study to evaluate the safety and immunogenicity 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 |
|---|---|
| NCOV 1002 Version 02 dated 02 July 2020 | 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.<br>Ahmadabad<br>GUJARAT<br>382481<br>India |
| **Phone** | 07948040000 |
| **Fax** | |
| **Email** | r.mittal@zyduscadila.com |

**Details Contact Person (Scientific Query)**

| Details Contact Person (Scientific Query) | |
|---|---|
| **Name** | Dr Kevinkumar Kansagra |
| **Designation** | Deputy General Manager |
| **Affiliation** | Cadila Healthcare Limited |
| **Address** | Zydus Research Center, Survey No. 396/403, Sarkhej-Bavla National Highway No.8A Moraiya, Ahmedabad - 382213<br>Ahmadabad<br>GUJARAT<br>382213<br>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<br>Ahmadabad<br>GUJARAT<br>382481<br>India |
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|---|---|
| **Phone** | 07948040000 |
| **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 Hari Shankar Gupta | VIMS Hospital | Kamptee Rd, LIC Square, Mohan Nagar, Nagpur, Maharashtra 440001<br>Nagpur<br>MAHARASHTRA | 9890924509<br><br>drhari_gupta@yahoo.com |
| Dr Parshottam Koradia | BAPS Pramukh Swami Hospital | Shri Pramukh Swami Maharaj Marg, Adajan char rasta. Adajan. Surat - 395 009 Gujarat, India<br>Surat<br>GUJARAT | 9825312027<br><br>purushottam_koradia@yahoo.co.in |
| Dr Vipul Prajapati | GCS Medical College, Hospital & Research Centre | Opposite DRM office, Near Chamunda Bridge, Naroda Road, Ahmedabad – 380025, Gujarat<br>Ahmadabad<br>GUJARAT | 9909912551<br><br>Prajapativipul1983@gmail.com |
| Dr Suresh Bhate | Jeevan Rekha Hospital | Dr. B.R. Ambedkar Road, Opp. Civil Hospital, Belagavi (Belgaum), Karnataka – 590002<br>Belgaum<br>KARNATAKA | 9845273830<br><br>drsureshgbhate@gmail.com |
| Dr Manish Kumar Jain | Maharaja Agrasen Superspeciality Hospital | Central Spine Agrasen Aspatal Marg, Sector No. - 7 Vidhyadhar Nagar, Jaipur, Rajasthan -302039<br>Jaipur<br>RAJASTHAN | 9414414834<br><br>doctormanishjain2@gmail.com |
| Dr Virendra Nath Tripathi | Prakhar Hospital Pvt. Ltd. | 8/219, Arya Nagar, Kanpur, Uttar Pradesh | 9415050777 |



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|---|---|---|---|
| | | 208002<br>Kanpur Nagar<br>UTTAR PRADESH | principalinvestigator1177@gmail.com |
| Dr Ajeet Pratap Singh | Rana Hospital Pvt. Ltd. | Rail Vihar, Medical College Road, Chargawa, Gorakhpur, Uttar Pradesh 273001<br>Gorakhpur<br>UTTAR PRADESH | 7652456810<br><br>ajeetpsingh1177@gmail.com |
| Dr Talati Kalpesh Chimanlal | Zydus Hospitals and Healthcare Research Pvt Ltd. | Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad, Gujarat 380054<br>Ahmadabad<br>GUJARAT | 9824014187<br><br>KALPESHTALATI@zydushospitals.com |
| Dr Taufik Momin | Zydus Research Centre | Survey No. 396/403, Opp. Sarvotam Hotel, Nr. Nova Petrochemicals, Sarkhej-Bavla N.H. No. 8A, Village: Moraiya, Ahmedabad 382213, Gujarat, India<br>Ahmadabad GUJARAT<br>Ahmadabad<br>GUJARAT | 02717665555<br><br>Taufik.Momin@zyduscadila.com |

**Details of Ethics Committee**

| Name of Committee | Approval Status | Date of Approval | Is Independent Ethics Committee? |
|---|---|---|---|
| BAPS Pramukh Swami Hospital Ethics Committee, BAPS Pramukh Swami Hospital, Adajan Cross Road. Adajan. Surat-395009 | Approved | 18/07/2020 | No |
| Ethics Committee Prakhar Hospital Pvt Ltd. Prakhar Hospital Pvt. Ltd. 8/219, Arya Nagar, Kanpur, Uttar Pradesh 208002 | Approved | 15/07/2020 | No |
| IEC Maharaja Agrasen Hospital, Maharaja Agrasen Superspeciality Hospital, Central Spine, Agrasen Aspatal Marg, Sector No. - 7 Vidhyadhar Nagar, Jaipur, Rajasthan -302039 | Approved | 19/07/2020 | No |
| Instituional Ethics Committee Jeevan Rekha Hospital Dr. B R Ambedkar Road Belgavi-590002 | Approved | 16/07/2020 | No |
| Institutional Ethics Committee of VIMS, | Approved | 20/07/2020 | No |



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| Mohan nagar, LIC Square, Kamptee Road, Nagpur 440001, Maharastra India. | | | |
| Institutional Ethics Committee Rana Hospital Pvt. Ltd., Rail Vihar Medical College Road, Chargawa Gorakhpur-273001 | Approved | 15/07/2020 | No |
| Institutional Ethics Committee, GCS Medical College, Hospital and Research Centre, Opp DRM Office, Nr Chamunda Bridge, Naroda Road, Ahmedabad-380025 | Approved | 29/07/2020 | No |
| Sangini Hospital Ethics Committee,C/o Sangini Hospital, First Floor,Santorini Square, b/h Abhishree Complex, Opp. Star Bazar, Nr. Jodhpur Cross Roads, Satellite, Ahmedabad-380015, Gujarat,India | Approved | 03/07/2020 | No |
| Zydus Hospital Ethics Commitee Zydus Hospitals and Healthcare Research Pvt Ltd., Zydus Hospitals Road, S.G. Highway, Thaltej, Ahmedabad, Gujarat 380054 | Approved | 27/07/2020 | No |

**Regulatory Clearance Status from DCGI**

| Status | Date |
|---|---|
| Approved/Obtained | 02/07/2020 |

**Health Condition / Problems Studied**

| Health Type | Condition |
|---|---|
| Healthy Human Volunteers | Healthy |

**Intervention / Comparator Agent**

| Type | Name | Details |
|---|---|---|
| Comparator Agent | Placebo in Phase Ii | 1)Dose:-0.1 ml in either of arm for Arm 1 (1 mg) with Needle and Arm 2(1 mg) with Pharmajet. In Arm 3 (2mg) with Needle and Arm 4(2mg) with Pharmajet,in both arm dose will given.(2)Frequency:-single time at day 0, day 28 and day 56.(3)Route: Intradermal |
| Intervention | nCov Vaccine | For Phase I: 1)Dose:-0.1 ml in either of arm for Arm 1 (1 mg) with Needle and Arm 2(1 mg) with Pharmajet. In Arm 3 (2mg) with Needle and Arm 4(2mg) with Pharmajet,in both arm dose |



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| | | will given..(2)Frequency:-single time at day 0 day 28 and day 56.(3)Route: Intradermal. For Phase II : (1)Dose:-0.1 ml in either of arm for Arm 1 (1 mg) with Needle and Arm 2(1 mg) with Pharmajet. In Arm 3 (2mg) with Needle and Arm 4(2mg) with Pharmajet,in both arm dose will given..(2)Frequency:-single time at day 0 day 28 and day 56.(3)Route: Intradermal. |

**Inclusion Criteria**

| Inclusion Criteria | |
|---|---|
| **Age From** | 18.00 Year(s) |
| **Age To** | 55.00 Year(s) |
| **Gender** | Both |
| **Details** | 1.Healthy male and non-pregnant, non-lactating female subjects between 18-55 years of age (both inclusive)<br/> 2.Body weight > 50 kg for male and > 45 kg for female and BMI within the range 18.5 - 29.9 kg/m2 (Both inclusive)<br/> 3.Able and willing to complete informed consent process with understanding of the purpose and procedures of the study <br/> 4.Subjects who, in the opinion of the Investigator, are healthy as determined by their pre study medical history, clinical examination, 12-lead ECG and clinical laboratory tests within the institutional normal range or judged as not clinically significant by the Investigator, including the following parameters: haematology, serum biochemistry, urinalysis, and serology<br/> 5.Subjects who can comply with trial procedures and who are available for the duration of follow up<br/> 6.Male subjects and female subjects of childbearing potential must practice highly effective contraception during the study and be willing and able to continue contraception for 90 days after administration of last study vaccine.<br/> <br/> For Phase II:-<br/> 1.Healthy subject of either gender ?12 years of age<br/> 2.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)<br/> 3.Adult subjects or parents of paediatric subjects literate enough to fill the diary card<br/> 4.Females of childbearing potential, must agree to use one of the approved contraception methods, from screening until completion of the follow-up visit and males will agree to use contraception.<br/> <br/> |

**Exclusion Criteria**

| Exclusion Criteria | |
|---|---|
| **Details** | For Phase I<br>1.Febrile illness (temperature ? 38°C or 100.4°F) or any acute illness or infection within 4 weeks of enrolment<br>2.History of confirmed SARS-CoV-2 positive<br>3.History of contact with a confirmed active SARS-CoV-2 positive patient within 14 days<br>4.History of SARS/ MERS infection<br>5.Subjects positive for antibody and antigen against SARS-CoV-2.<br>6.Previous participation in any clinical trial of a SARS-CoV-2 candidate vaccine<br>7.Any clinically significant laboratory or ECG findings during screening or check-in<br>8.History or presence of significant smoking (?10 cigarettes per day)<br>9.Systolic blood pressure more than 140 mmHg and less than 100 mmHg and diastolic blood pressure more than 90 mmHg and less than 60 mmHg.<br>10.History of, or positive screening test for, hepatitis C infection |

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| | (defined as positive for hepatitis C virus antibody), hepatitis B infection (defined as positive for hepatitis B surface antigen), or human immunodeficiency virus I or II<br><br>For Phase II<br>1.Febrile illness (temperature ? 38°C or 100.4°F) or any acute illness or infection within 4 weeks of enrolment<br>2.History of confirmed SARS-CoV-2 positive<br>3.History of contact with a confirmed active SARS-CoV-2 positive patient within 14 days<br>4.History of SARS/ MERS infection<br>5.Subjects positive for antibodies against SARS-CoV-2 on antibody detection test at the time of screening<br>6.Previous participation in any clinical trial of a SARS-CoV-2 candidate vaccine<br>7.Past history of hypersensitivity reaction or any serious adverse event after any vaccination<br>8.Subjects with thrombocytopenia or any coagulation disorder, or subjects on anticoagulation therapy |

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| **Method of Generating Random Sequence** | Computer generated randomization |
| **Method of Concealment** | Other |
| **Blinding/Masking** | Outcome Assessor Blinded |

**Primary Outcome**

| Outcome | Timepoints |
|---|---|
| Phase I:-To evaluate the safety of Novel Corona Virus-2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects.<br><br>Phase II:-To evaluate the immunogenicity of Novel Corona Virus-2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects compared to placebo. | Phase I: Day 0 and Day 84<br>Phase II: Day 0 and Day 224 |

**Secondary Outcome**

| Outcome | Timepoints |
|---|---|
| Phase I:-1)To evaluate the safety of Novel Corona Virus-2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects.<br>Phase II:-1)To evaluate the safety of Novel Corona Virus-2019-nCov Vaccine Candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects compared to placebo. | Phase I: Day 0 and Day 84<br>Phase II: Day 0 and Day 224 |

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| **Target Sample Size** | **Total Sample Size=**1048<br>**Sample Size from India=**1048<br>**Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials<br>**Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials |
| **Phase of Trial** | Phase 1/ Phase 2 |
| **Date of First Enrollment (India)** | 13/07/2020 |
| **Date of First Enrollment (Global)** | No Date Specified |
| **Estimated Duration of Trial** | **Years=**1<br>**Months=**0<br>**Days=**0 |



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| **Recruitment Status of Trial (Global)** | Not Applicable |
| **Recruitment Status of Trial (India)** | Closed to Recruitment of Participants |
| **Publication Details** | NIL |
| **Brief Summary** | 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.<br><br>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. |