Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 13:27:06 GMT)

CTRI Number	CTRI/2021/04/032688 [Registered on: 08/04/2021] - **Trial Registered Prospectively**
Last Modified On	23/06/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Safety and immunogenicity study of mRNA based vaccine (HGCO19) against COVID-19 in healthy adult participants.
Scientific Title of Study	Randomized, Phase I/II, Placebo-controlled, Dose-Ranging, study to evaluate the Safety, Tolerability and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy adult subjects.

Secondary IDs if Any

Secondary ID	Identifier
GBL/HGCO19/2020/01; Version 1.0 Dated 11 Nov 2020	Protocol Number

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

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Amit Saraf
Designation	Assistant General Manager
Affiliation	Gennova Biopharmaceuticals Limited
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Details Contact Person (Public Query)

Details Contact Person (Public Query)	
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Designation	Assistant General Manager
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	India
Phone	02039166300
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Gennova Biopharmaceuticals Limited, Block 1, Plot No. P-1 and P-2, ITBT Park, Phase-II, MIDC, Hinjawadi, Pune- 411057

Primary Sponsor

Primary Sponsor Details	
Name	Gennova Biopharmaceuticals Limited
Address	Gennova Biopharmaceuticals Limited, Block 1, Plot No. P-1 and P-2, ITBT Park, Phase-II, MIDC, Hinjawadi, Pune- 411057, Maharashtra
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 Prakash Shende	Dr. D.Y. Patil Medical College Hospital and Research Center	Sant Tukaram Nagar, Pimpri Pune MAHARASHTRA	09822246881 drprakashshende1979@gmail.com
Dr Abhishek B Agarwal	Guru Nanak Hospital	Shiv Colony, Opposite old Palwal bus stand, Main Delhi, Mathura National Highway, Palwal Faridabad HARYANA	9582366630 abhishek.agarwal@inclentrust.org
Dr Pradeep DCosta	KEM Hospital Research Center	KEM Hospital Research Center, Sardar Moodliar Road, Rasta Peth, Pune MAHARASHTRA	09822632812 pradeepdcosta@yahoo.co.in
Dr Vijaykumar B Barge	Rajashree Chhatrapati Shahu Maharaj Govt. Medical College	Dasara Chowk, Town Hall, Bhausingji road, Kolhapur MAHARASHTRA	09011066766 drvijaybarge12@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee, Dr. D.Y. Patil Vidyapeeth, Pimpri, Pune	Approved	22/05/2021	No
INCLEN Independent Ethics Committee	Submittted/Under Review	No Date Specified	Yes
Institutional Ethics Committee II, RCSMGMC and CPR Hospital, Kolhapur	Approved	02/04/2021	No
KEM Hospital Research Centre Ethics Committee, Pune	Approved	01/04/2021	No

Regulatory Clearance

Status from DCGI

Status	Date
Approved/Obtained	25/01/2021

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Active immunization for prevention of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection

Intervention / Comparator Agent

Type	Name	Details
Intervention	HGCO19 (COVID-19 vaccine)	Novel mRNA-based candidate vaccine candidate, using Spike (S)-protein of the virus as antigen. HGCO19 will be administered IM at day 1 and day 29.
Comparator Agent	Placebo	Two doses of 0.5 ml of placebo (buffer), administered Intramuscularly at 4-weeks apart.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	75.00 Year(s)
Gender	Both
Details	Applicable for both phases of study: 1. Male and female subjects aged between 18 to 70 years (Phase I) / 18 to 75 years (Phase II) (both inclusive) at randomization. 2. Healthy as judged by medical history, physical and other examination or investigations and in the clinical opinion of the Investigator. 3. Subject should be capable and willing to give voluntary written informed consent prior to inclusion in the study. 4. Able to comprehend and comply with study requirements and procedures and be able and willing to complete subject diary. 5. Negative / Non-reactive for antibodies against SARS-CoV-2. 6. Negative / Non-reactive RT-PCR screening of nasopharyngeal swabs/suitable sample for SARS CoV-2 within 72 hours prior vaccination. 7. Male subjects who are sexually active or married and female subjects who are sexually active or married and are of child bearing potential should be willing to follow effective birth control methods for duration of the study. Note: Birth control methods include vasectomised subject/partner; or any 2 of the following methods: intrauterine device; oral, transdermal, injected, or implanted contraceptive; condoms; occlusive cap (diaphragm or cervical vault caps); spermicidal foam/gel/cream, etc. OR Exception to the above are male subjects who are infertile (post vasectomy with documented azoospermia or bilateral orchidectomy) and female subjects who are of non-childbearing potential [who are surgically sterile (hysterectomy, bilateral tubal ligation or bilateral salpingo-oophorectomy) or postmenopausal subjects with amenorrhea for at least 2 years]

Exclusion Criteria

Exclusion Criteria	
Details	Exclusion Criteria for Phase I: 1. Subject with a medical history of COVID-19 infection or who has received vaccine to prevent COVID-19 infection. 2. Subjects with a BMI > 30 kg/m2 3. Protocol defined laboratory assessments outside the range/limit defined in Appendix 2. Any other laboratory value if ? Grade 2 as per DAIDs criteria. Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events, corrected version 2.1, July 2017, of the

US National Institutes of Health
4. Any illness or any other current or pre-existing health condition (e.g. any major pulmonary, cardiovascular, renal, neurological, metabolic, gastro-intestinal, hepato-biliary, haematological functional abnormality, mental or physical disability, blood dyscrasia, major congenital defects, etc.) which in the opinion of the Investigator may affect the safety of the subject or the study endpoints.
5. Individuals currently working in occupations with high risk of exposure to SARS-CoV-2 (e.g. healthcare worker in direct care of COVID-19 patients, front line workers in COVID 19 hotspots / outbreak areas).
6. History of allergic/hypersensitivity reactions or anaphylaxis to any vaccine or components of study vaccine.
7. Subject has any acute illness (moderate or severe) at the time of vaccination and/or fever (oral temperature ?38°C or ?100.4 °F) within 48 hours prior to vaccination.
8. History of cancer, organ transplant, any other clinically significant immunosuppressive condition or autoimmune disease.
9. Subject has uncontrolled chronic disease including asthma, diabetes (HbA1c of >9%), hypertension (Systolic Blood pressure of >160 mm of Hg and/ or Diastolic Blood Pressure of >100 mm of Hg), thyroid disorder as assessed by the Investigator.
10. Subjects who are pregnant or breast feeding or willingness/intention to become pregnant during the study.
11. Prior major surgery or any radiation therapy within 4 weeks of Screening visit.
12. Positive serologic test for HIV 1 and 2, HBsAg or HCV.
13. Current (within 14 days prior to Screening visit) or anticipated concomitant immune modifying or immunosuppressive therapy (excluding inhaled, topical skin or eye drop-containing corticosteroids, low-dose methotrexate, or corticosteroids at a dose less than 20 mg/day).
14. Planned or actual receipt of any vaccine other than the study intervention within 30 days before and after each study vaccination.
15. Eczema or other significant skin lesion or infection at the site of vaccination.
16. Administration of blood, blood products and/or plasma derivatives or any immunoglobulin preparation 90 days prior to screening visit.
17. Bleeding diathesis or condition associated with prolonged bleeding.
18. Participating in another clinical trial within 30 days prior to Screening visit or planning to participate in another clinical trial during the study duration or planning to migrate.
19. Any other condition which in the opinion of the Investigator may affect subject’s safety or participation.

Exclusion Criteria for Phase II:
1. Subject with a medical history of COVID-19 infection or who has received vaccine to prevent COVID-19 infection.
2. Any clinically significant laboratory values or illness or any other current or pre-existing health condition (e.g. any major pulmonary, cardiovascular, renal, neurological, metabolic, gastro-intestinal, hepato-biliary, haematological functional abnormality, mental or physical disability, blood dyscrasia, major congenital defects, etc.) which in the opinion of the Investigator may affect the safety of the subject or the study endpoints.
3. History of allergic/hypersensitivity reactions or anaphylaxis to any vaccine or components of study vaccine.
4. Subject has any acute illness (moderate or severe) at the time of vaccination and/or fever (oral temperature ?38°C or ?100.4 °F) within

	48 hours prior to vaccination. 5. History of cancer, organ transplant, any other clinically significant immunosuppressive condition or autoimmune disease. 6. Subject has uncontrolled chronic disease including asthma, diabetes (HbA1c of >9%), hypertension (Systolic Blood pressure of >160 mm of Hg and/ or Diastolic Blood Pressure of >100 mm of Hg), thyroid disorder as assessed by the Investigator. 7. Subjects who are pregnant or breast feeding or willingness/intention to become pregnant during the study. 8. Prior major surgery or any radiation therapy within 4 weeks of Screening visit. 9. Positive serologic test for HIV 1 and 2, HBsAg or HCV. 10. Current (within 14 days prior to Screening visit) or anticipated concomitant immune modifying or immunosuppressive therapy (excluding inhaled, topical skin or eye drop-containing corticosteroids, low-dose methotrexate, or corticosteroids at a dose less than 20 mg/day). 11. Planned or actual receipt of any vaccine other than the study intervention within 30 days before and after each study vaccination. 12. Eczema or other significant skin lesion or infection at the site of vaccination 13. Administration of blood, blood products and/or plasma derivatives or any immunoglobulin preparation 90 days prior to screening visit. 14. Bleeding diathesis or condition associated with prolonged bleeding. 15. Participating in another clinical trial within 30 days prior to Screening visit or planning to participate in another clinical trial during the study duration or planning to migrate. 16. Any other condition which in the opinion of the Investigator may affect subject's safety or participation.

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

Primary Outcome

Outcome	Timepoints
1. Occurrence and severity of local reactogenicity AEs for 7 days following each dose of vaccination. 2. Occurrence, severity and relationship of systemic reactogenicity AEs for 7 days following each dose of vaccination. 3. Occurrence, severity and relationship of unsolicited AEs up to 28 days following each dose of vaccination. 4. Occurrence of SAE at any time during study participation. 5. Changes in safety assessments including laboratory parameters and vital signs from baseline.	Occurrence of solicited AEs within 7 days post each dose of vaccine. Occurrence of Unsolicited AEs upto 28 days post each dose of vaccine (day 29 and day 57). SAEs thorough out the duration of the study.

Secondary Outcome

Outcome	Timepoints
1. Geometric mean titer (GMT) as measured by IgG-ELISA to SARS-CoV-2 Spike protein and against the RBD of Spike protein at Day 57 (28 days post Dose 2). 2. Geometric mean fold rise (GMFR) in SARS CoV-2 Spike protein-specific binding antibody	At day 57.

(IgG) levels and in RBD of Spike protein IgG levels from baseline at Day 57.	
Exploratory Outcomes: 1. GMT of SARS-CoV-2 specific serum neutralizing antibody levels as measured by pseudovirus/ surrogate virus neutralization assay at Day 29 (before Dose 2), Day 57, Day 119 and Day 209. 2. GMT of SARS-CoV-2 specific serum neutralizing antibody levels as measured by live virus SARS-CoV-2 neutralization assay [Plaque Reduction Neutralization Test (PRNT)] at Day 29, Day 57, Day 119 and Day 209.	At day 29, day 57, day 119 and day 209.
Exploratory Outcomes: 3. Relationship (correlation analysis) between SARS-CoV-2 neutralizing antibody and S-protein and RBD of S-protein IgG titers at Days 29, 57, 119, and 209. 4. GMT as measured by IgG-ELISA to SARS-CoV-2 S-protein and against the RBD of S-protein at Days 29, 119 and 209. 5. GMT as measured by IgM-ELISA to SARS-CoV-2 S-protein at Days 29, 57, 119, and 209. 6. SARS-CoV-2 Spike protein specific T-cell responses as measured by flow cytometry at Days 29, 57, 119, and 209.	At day 29, day 57, day 119 and day 209.
Exploratory Outcome: 7. Number of subjects with laboratory confirmed COVID-19 infection during study participation.	Throughout the study duration.

Target Sample Size	**Total Sample Size=**620 **Sample Size from India=**620 **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)	19/04/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**2 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	Not Available
Brief Summary	This is a dose ranging, placebo-controlled, Phase I/II study in healthy adult subjects. The study will evaluate escalating dose strengths of HGCO19 administered intramuscularly as a two-dose regimen 28 days apart. Phase-1 study is a randomized, open-label, placebo-controlled, multi-centre study to assess the safety and immunogenicity of HGCO19 vaccine. Phase-1 study will enrol 120 healthy participants in the age group of 18-70 years. Phase II study is a randomized, observer-blind, placebo-controlled, multi-centre study to assess safety and immunogenicity of HGCO19 in comparison to placebo. In the Phase-2 study, approximately 500 healthy subjects in the age group of 18 to 75 years will be enrolled.