Clinical Trial Details (PDF Generation Date :- Sun, 25 Apr 2021 16:58:26 GMT)

CTRI Number	CTRI/2020/11/029234 [Registered on: 19/11/2020] - **Trial Registered Prospectively**
Last Modified On	08/02/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Multi-centre, phase II/III adaptive clinical trial to assess safety and immunogenicity of Gam-COVID-Vac combined vector vaccine
Scientific Title of Study	Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multi-Centre Phase II/III Adaptive Clinical Trial to Assess the Safety and Immunogenicity of Gam-COVID-Vac Combined Vector Vaccine for SARS-?ov-2 Infection in Indian Healthy Subjects

Secondary IDs if Any

Secondary ID	Identifier
RDI-GCV-001 V3.0 dated 19 Oct 2020	Protocol Number

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

Details of Principal Investigator	
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Details Contact Person (Scientific Query)	
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Source of Monetary or Material Support

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> Dr. Reddy's Laboratories Limited, Integrated Product Development, Innovation Plaza, Survey No 42, 45 & 46, Bachupally Village, Bachupally Mandal, Medchal, Malkajgiri District, Hyderabad – 500090

Primary Sponsor

Primary Sponsor Details	
Name	Human Vaccine LLC
Address	Capital City, South Tower, 8, Building. 1, Floor 7, Room I, part of Room 3, workstation 7.31, Presnenskaya Naberezhnaya, 123112, Russia
Type of Sponsor	Government funding agency

Details of Secondary Sponsor

Name	Address
Dr Reddys Laboratories Limited	Integrated Product Development, Innovation Plaza, Survey No 42, 45 & 46, Bachupally Village, Bachupally Mandal, Medchal, Malkajgiri District, Hyderabad – 500090

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr P Naveen Reddy	AIG Hospitals	AIG Hospitals, No. 136, Plot No 2/3/4/5 Survey, 1, Mindspace Rd, Gachibowli, Hyderabad, Telangana 500032 Hyderabad TELANGANA	919848045814 drnaveen.reddy@aighospitals.com
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		TAMIL NADU	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethics Committee, Maharaja Agrasen Hospital, Jaipur	Approved	12/11/2020	No
Ethics Committee GSVM Medical College	Approved	13/11/2020	No
INCLEN Independent Ethical Committee	Approved	21/01/2021	Yes
Institutional Ethics Committee , Atharva Hospital	Approved	15/11/2020	No
Institutional Ethics Committee , Noble Hospital	Approved	11/11/2020	No
Institutional Ethics Committee , Sehgal Nursing Home	Approved	27/11/2020	No
Institutional Ethics Committee Asian Institute of Gastroenterology	Approved	30/12/2020	No
Institutional Ethics Committee –Clinical studies Indraprastha Apollo Hospitals	Approved	05/01/2021	No
Institutional Ethics Committee College of Medicine and Sagore Dutta Hospital	Approved	11/01/2021	No
Institutional Ethics Committee Grant Government Medical College & Sir J J Group of Hospitals	Approved	27/11/2020	No
Institutional Ethics committee of B.J.G.M.C.& Sassoon General Hospital	Approved	22/01/2021	No
Institutional Ethics Committee Tirunelveli Medical College	Approved	17/01/2021	No
Institutional Ethics Committee, BAPS Pramukh Swami Hospital	Approved	15/12/2020	No
Institutional Ethics Committee, KAHER JNMC Campus	Approved	02/12/2020	No
Institutional Ethics Committee, S. N. Medical College, Agra	Approved	31/12/2020	No
Institutional Ethics Committee. JSS	Approved	01/01/2021	No

Medical College & Hospital			
Institutional Review Board, Christian Medical College	Approved	31/12/2020	No
Jamia Hamdard Institutional Ethics Committee	Approved	03/01/2021	No
KEM Hospital Research Centre Ethics Committee	Approved	19/01/2021	No
Mahatma Gandhi Missions Ethics Committee for Research on Human Subject	Approved	11/12/2020	No
Peerless Hospitex Hospital and Research Center Limited Clinical Research Ethics Committee	Approved	18/12/2020	No
PIMS Institute Ethics Committee	Approved	18/01/2021	No
Rhythm Heart Institute Ethics Committee	Approved	02/01/2021	No
Scientific Research and Ethics Review Committee Batra Hospital and Medical Research Centre	Approved	06/01/2021	No
Sumandeep Vidyapeeth Institutional Ethics Committee	Approved	04/01/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	22/10/2020

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	COVID-19 negative

Intervention / Comparator Agent

Type	Name	Details
Intervention	Component I	Recombinant adenovirus serotype 26 particles containing the SARS-CoV-2 protein S gene, in the amount of (1.0 +/-0.5) ? 10 raise to 11 particles per dose of 0.5 mL.
Intervention	Component II	Recombinant adenovirus serotype 5 particles containing SARS-CoV-2 protein S gene, in the amount of (1.0 +/-0.5) ? 10raise to 11 particles per dose of 0.5 mL
Comparator Agent	Placebo Component I	Matching product without Recombinant adenovirus particles containing the SARS-CoV-2 protein S gene
Comparator Agent	Placebo Component II	Matching product without

		Recombinant adenovirus particles containing the SARS-CoV-2 protein S gene

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Written informed consent of a subject to participate in the trial 2. Males and females aged 18+ years 3. Negative human immunodeficiency virus (HIV 1 & 2) and hepatitis B and C test results 4. Negative immunoglobulin M (IgM) and immunoglobulin G (IgG) SARS-CoV-2 antibodies through enzyme immunoassay test result 5. Negative COVID-2019 Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) test result at the screening visit (72 hours prior to Visit 1 [Day 1]) 6. No COVID-2019 in the medical history 7. History of no contact with COVID-2019 persons within at least 14 days before the enrolment (according to subjects) 8. Consent for using effective methods of contraception during the entire trial1 9. Negative urine pregnancy test at the screening visit (for child-bearing age women) 10. No evident vaccine-induced reactions or complications after receiving immunobiological products in the medical history 11. No acute infectious and/or respiratory diseases within at least 14 days before the enrolment.

Exclusion Criteria

Exclusion Criteria	
Details	1. Any vaccination/immunization within 30 days before the enrolment 2. Steroids (except hormonal contraceptives) and immunoglobulins or other blood products therapy not finished 30 days before the enrolment 3. Immunosuppressors therapy finished within 3 months before the enrolment 4. Pregnancy or breast-feeding 5. Acute coronary syndrome or stroke suffered less than one year before the enrolment 6. Tuberculosis, chronic systemic infections 7. Drug allergy (anaphylactic shock, Quincke edema, polymorphic exudative eczema, atopy, serum disease), hypersensitivity or allergic reaction to immunobiological products, known allergic reactions to study product components, acute exacerbation of allergic diseases on the enrolment day 8. Subjects who are on drugs that could have potential drug interactions with adenovirus vaccine 9. Medical history of malignancy 10. Donated blood or plasma (450+ mL) within 2 months before the enrolment 11. Splenectomy in the medical history 12. Neutropenia (absolute neutrophil count less than 1,000 mm3), agranulocytosis, significant blood loss, severe anaemia (haemoglobin less than 80 g/L), immunodeficiency including autoimmune disorders in the medical history within 6 months before the enrolment 13. Active form of a disease caused by the HIV and hepatitis B or C 14. Anorexia, protein deficiency of any origin 15. Tattoos at the injection site (deltoid muscle area), which does not allow assessing the local response to the IMP or placebo administration 16. Alcohol or drug addiction in the medical history. 17. Participation in any other interventional clinical trial within 1 month prior to the Screening

	18. Any other medical condition that would limit the participation of the subject as per Investigator discretion 19. Study centre staff or other employees directly involved in the trial and their families 20. Subjects contraindicated for vaccination

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Pre-numbered or coded identical Containers
Blinding/Masking	Double Blind Double Dummy

Primary Outcome

Outcome	Timepoints
Phase II-Incidence & severity of AEs,Seroconversion rate of SARS-CoV-2 glycoprotein-specific antibodies Phase III-Incidence of SAEs following vaccination during the study, GMT ratio of SARS-CoV-2 glycoprotein-specific antibodies in immunogenicity group	Phase II-At day 28, Phase III-Entire study duration,At day42

Secondary Outcome

Outcome	Timepoints
Incidence of AEs & SAEs, Clinically significant changes. GMT & Seroconversion rate of SARS-CoV-2 glycoprotein-specific & SARS-CoV-2 VNA antibodies in immunogenicity. Interferon gamma concentration in T-cells after restimulation with the SARS-CoV-2 glycoprotein in CMI, Number of proliferating CD4 and CD8 cells in response to mitogen stimulation & their ratios in CMI, % of subjects with antibodies to SARS-CoV-2 N-protein.Incidence of cases of Covid-19 developed	Entire study duration, Baseline (GMT), Day21,28,90,180 Baseline,Day28,42,90,180, Day 42 and 180

Target Sample Size	**Total Sample Size=**1600 **Sample Size from India=**1600 **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 2/ Phase 3
Date of First Enrollment (India)	01/12/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**7 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	Not Applicable
Brief Summary	Randomized, Double-Blind, Placebo-Controlled, Parallel-Group,

Multi-Centre Phase II/III Adaptive Clinical Trial to Assess the Safety and Immunogenicity of Gam-COVID-Vac Combined Vector Vaccine for SARS-?ov-2 Infection in Indian Healthy Subjects.

The IMP/placebo will be administered intramuscularly during vaccination visits:

At the Visit 1 (Day 1) the subject will receive component I of the IMP/placebo from the bottle marked with the Roman number I. Component II of the IMP/placebo will be administered during the Visit 3 (Day 21±2) from the bottle marked with the Roman number II.

1600 subjects planned for this trial (100 in phase II and 1500 in phase III).