Clinical Trial Details (PDF Generation Date :- Fri, 27 Jan 2023 19:09:04 GMT)

CTRI Number	CTRI/2021/08/036074 [Registered on: 31/08/2021] - **Trial Registered Prospectively**
Last Modified On	18/03/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Biological E's CORBEVAX vaccine clinical study for protection against Covid-19 disease.
Scientific Title of Study	A Prospective, Single-blind, Randomized, Active-controlled Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to RT-PCR Negative Adult Subjects.

Secondary IDs if Any

Secondary ID	Identifier
BECT/COVID-19-PHASE-III/074 Ver:1.1 Dated:19.08.21	Protocol Number

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

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Biological E.Limited, 18/1&3, Azamabad, Hyderabad - 500020, Telangana, India.

Primary Sponsor

Primary Sponsor Details	
Name	Biological E Limited
Address	18/1&3, Azamabad, Hyderabad - 500020, Telangana, India.
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
None	None

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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Details of Ethics

Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
BAPS Hospital Institutional Ethics Committee	Approved	06/09/2021	No
Drug Trial Ethics Committee - Dayanand Medical College and Hospital,	Submittted/Under Review	No Date Specified	No
Ethics Committee - Guru Teg Bahadur Hospital	Approved	14/09/2021	No
Ethics Committee - St. Theresas Hospital	Approved	30/08/2021	No
IEC - BJ Medical College	Submittted/Under Review	No Date Specified	No
IEC - King George Hospital	Submittted/Under Review	No Date Specified	No
IEC - NIMS University	Approved	11/09/2021	No
IEC IMS and SUM Hospital	Submittted/Under Review	No Date Specified	No
IEC Intervention Studies - JIPMER	Submittted/Under Review	No Date Specified	No
IEC Prakhar Hospital Pvt Ltd	Approved	30/08/2021	No
IEC, Mahatma Gandi Institute Of Medical Sciences	Approved	04/09/2021	No
IEC-AIIMS-Patna,	Approved	09/09/2021	No
Institutional Ethics Committee - Apex Hospitals Private Limited	Approved	09/09/2021	No
Institutional Ethics Committee - Christian Medical College & Hospital	Approved	25/09/2021	No
Institutional Ethics Committee - Grant Medical College & Sir J.J Hospital	Approved	13/09/2021	No
Institutional Ethics Committee - Jawahar Lal Nehru Medical College	Approved	21/09/2021	No
Institutional Ethics Committee - JSS Medical College and Hospital	Approved	16/09/2021	No
Institutional Ethics Committee - KLE University	Approved	03/09/2021	No
Institutional Ethics Committee - TNMC Nair Hospital,	Submittted/Under Review	No Date Specified	No
Institutional Ethics	Submittted/Under	No Date Specified	No

Committee - Yashwantrao Chavan Memorial Hospital	Review		
Institutional Ethics Committee -SRIHER	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee for ESIC Medical College And Hospital	Approved	30/08/2021	No
Institutional Ethics Committee III - Tata Memorial Centre ACTREC,	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Belagavi Institute Of Medical Sciences	Approved	13/09/2021	No
Institutional Ethics Committee- Asian Institute of Gastroenterology	Approved	14/09/2021	No
Institutional Ethics Committee- Government Medical College and Hospital,	Submittted/Under Review	No Date Specified	No
IRB Christian Medical college	Approved	30/09/2021	No
Medanta Institutional Ethics Committee	Approved	30/09/2021	No
Samvedna Hospital Ethics Committee	Approved	11/09/2021	No
Shubham Sudbhawana Superspeciality Hospital Ethics Committee	Approved	04/09/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	20/08/2021

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Active immunization for the prevention of COVID-19 disease

Intervention / Comparator Agent

Type	Name	Details
Intervention	Biological E's CORBEVAX Vaccine	Dose: 0.5ml, Route of administration: Intramuscular injection, Frequency: Two doses at Day 0 and Day 28.
Comparator Agent	Serum Institute of India Pvt. Ltd's- COVISHIELD	Dose: 0.5ml, Route of administration: Intramuscular injection, Frequency: Two doses at Day 0 and Day 28.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	1. Subject is seronegative to anti-SARS-CoV-2 IgG antibody prior to randomisation either into Group-1 and Group-2. 2. Subject is

	virologically seronegative to SARS-CoV-2 infection as confirmed by RT-PCR prior to enrolment in all groups. 3. Male or female subject between ? 18 to 80 years of age. 4. Subject is willing to provide a written informed consent for voluntary participation in the study. 5. Subject, in the opinion of the investigator, has ability to communicate and willingness to comply with the requirements of the protocol. 6. Subject is seronegative to HIV 1 & 2, HBV and HCV infection prior to enrolment. 7. Subject is considered of stable health as judged by the investigator, determined by medical history and physical examination. 8. Female subject of child bearing potential must have a negative urine pregnancy test (UPT), and willingness to avoid becoming pregnant through use of an effective method of contraception or abstinence from the time of study enrolment until six weeks after the last dose of vaccination in the study. 9. Male subject, who is sexually active, must agree to use double-barrier contraception (e.g. condom with spermicide) with his female partner during the study period. Male subject should also agree to avoid semen donation or providing semen for in-vitro fertilization during the study duration. 10. Subject agrees not to participate in another clinical trial at any time during the total study period. 11. Subject agrees to refrain from blood donation during the course of the study. 12. Subject agrees to remain in the town where the study centre is located, for the entire duration of the study.

Exclusion Criteria

Exclusion Criteria	
Details	1. History of vaccination with any investigational or approved vaccine against COVID-19 disease. 2. Subject living in the same household as that of any active COVID-19 positive individual. 3. History of receipt of any licensed vaccine within 1 month prior to screening, likely to impact on interpretation of the trial data (e.g., influenza vaccines); 4. Subjects with any clinically significant abnormal haematology and biochemical laboratory parameters tested at screening as judged by the investigator. 5. Subjects with Body temperature of ?100.4°F (>38.0°C) or symptoms of an acute illness at the time of screening or prior to vaccination. 6. Pregnant women, nursing women or women of childbearing potential who are not actively avoiding pregnancy during the study. 7. Subjects with known current or chronic history of any of the following conditions, likely to affect participation in the study: 8. severe psychiatric conditions; 9. any bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder); 10. allergic disease or reactions likely to be exacerbated by any component of the study vaccine (BE SARS-CoV-2 COVID-19 vaccine); 11. neurological illness, and any other serious chronic illness requiring hospital specialist supervision. 12. Subjects requiring chronic administration (defined as more than 14 days in total) of immunosuppressant (e.g. corticosteroids, cytotoxic drugs or antimetabolites, etc.) or other immune-modifying drugs (e.g. interferons) during the period starting six months prior to the first vaccine dose including use of any blood products. 13. For corticosteroids, this will mean prednisone ?0.5 mg/kg/day, or equivalent. 14. Inhaled and topical steroids are allowed. 15. Receipt of prohibited concomitant medication that may jeopardize the safety of the participant or interpretation of the data.

	16. Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required). 17. Any medical condition that in the judgment of the investigator would make study participation unsafe. 18. Planned use of any investigational or non-registered product other than the study vaccine during the trial period or 3 months prior to enrolment. 19. Current or planned participation in prophylactic drug trials for the duration of the study. 20. Individuals who are part of the study team or close family members of individuals conducting the study.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	On-site computer system
Blinding/Masking	Participant Blinded

Primary Outcome

Outcome	Timepoints
1.Immune response measured after completion of 2-dose immunization schedule, as determined by geometric mean titres (GMT/C) of SARS-CoV-2 specific neutralising antibodies to evaluate immunogenic superiority	1. After 14 days

Secondary Outcome

Outcome	Timepoints
Immune response measured after completion of 2-dose immunization schedule, as determined by geometric mean titres (GMT/C) of SARS-CoV-2 specific neutralising antibodies to evaluate immunogenic non-inferiority	After 14 days
Immune response against Beta and Delta variants in terms of geometric mean virus neutralising antibody (VNA) titre and Fold Reduction of VNA titer from Wuhan strain to Beta or Delta strain. Geometric Mean Fold Reduction will be calculated	At Day 42
Occurrence and severity of any adverse reactions	Within 60 minutes of post vaccination
Occurrence and severity of any solicited symptoms	Within 7 consecutive days
Occurrence and severity of any unsolicited adverse events	Till 28 days' post vaccination period
Occurrence and severity of any SAEs or medically attended AEs or AEs of special interest (AESIs)	Until 6 months post 2nd dose

Target Sample Size	**Total Sample Size=**2140 **Sample Size from India=**2140 **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)	03/09/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**10

	Days=0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	None
Brief Summary	This is a prospective, multicentre single-blind, randomized, active-controlled phase III clinical study. A total of 2140 eligible volunteers of either gender, aged 18 to 80 years, will be enrolled in this Phase III study. All the subjects enrolled into the trial will be assessed for overall safety, reactogenicity and tolerability at each of the protocol specified visits till end of the study. The immunogenicity assessment would be to demonstrate immunogenicity in terms of both neutralising and IgG ELISA antibody titres of Test vaccine and their comparability with Comparator vaccine in the immunogenicity population. The study will be conducted in compliance with GSR 227(E), ICH and Indian good clinical practice guidelines in force at the time of study conduct.