FULL DETAILS (Read-only) -> Click Here to Create PDF for Current Dataset of Trial

CTRI Number	**CTRI/2021/06/034014** [Registered on: 04/06/2021] **Trial Registered Prospectively**
Last Modified On:	03/08/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Single Arm Trial
Public Title of Study	Biological E's CORBEVAX vaccine clinical study for protection against Covid-19 disease.
Scientific Title of Study	A Prospective, multicentre, Phase II Seamlessly Followed by 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 COVID-19-Negative Adult Subjects.
Trial Acronym	None
Secondary IDs if Any	**Secondary ID** / **Identifier** BECT/COVID-19-PHASE-III/069 Ver: 2.1 dated:13.05.21 / Protocol Number
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	**Name**: Dr Subhash Thuluva **Designation**: Vice President - Clinical Development **Affiliation**: Biological E.Limited **Address**: Clinical Development Dept, 2nd floor, Road No.35, Jubilee Hills Hyderabad TELANGANA 500033 India **Phone**: 04071216248 **Fax**: 04027675309 **Email**: subhash.thuluva@biologicale.com
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Source of Monetary or Material Support	Biological E.Limited, 18/1&3, Azamabad, Hyderabad - 500020, Telangana, India.

Primary Sponsor	**Name**	Biological ELimited
	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	India

Sites of Study

No of Sites = **15**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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Details of Ethics Committee Modification(s)

No of Ethics Committees= **15**

Name of Committee	Approval Status
Ethical Committee, Mahatma Gandhi Medical College and Research Institute	Submittted/Under Review
Ethics Committee downtown hospital	Submittted/Under Review
Ethics Committee, St. Theresa's Hospital	Approved
Guru Teg Bahadur Hospital Ethics Committee	Approved
IEC ESIC Medical College and Hospital,	Approved
IEC Prakhar Hospital Pvt Ltd	Approved
IEC, All India Institute of Medical Sciences, Patna	Approved
IEC, Maharaja Agrasen Hospital	Approved
Institutional Ethics Committee of AH and RC Adichunchanagiri Hospital and Research Center	Approved

Institutional Ethics Committee S.N Medical college	Submittted/Under Review
Institutional Ethics Committee, IMS & SUM Hospital	Approved
Institutional Ethics committee, KLES Dr. Prabhakar Kore Hospital	Approved
Institutional Ethics Committee- AIG Hospital	Approved
Pagarav Ethics committee	Approved
Tagore Hospital Ethics Committee	Approved

Regulatory Clearance Status from DCGI

Status
Approved/Obtained

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 SARS-CoV-2 (COVID-19)Vaccine-CORBEVAX	Dose: 0.5ml, Route of administration: Intramuscular injection, Frequency: Two doses at Day 0 and Day 28.
Comparator Agent	None	None

Inclusion Criteria

Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	Inclusion Criteria ONLY for Phase II: 1.Male or female (non-pregnant) subject between ≥ 18 to 55 years of age. 2.Subject seronegative to anti-SARS-CoV-2 antibody prior to enrolment. Inclusion Criteria ONLY for Phase III: 1.Male or female subject between ≥ 18 to 80 years of age. Inclusion Criteria for Phase II and Phase III: 1.Subject or their legally acceptable representative (LAR) is willing to provide a written informed consent for voluntary participation in the study. 2. Subject, in the opinion of the investigator, has ability to communicate and willingness to comply with the requirements of the protocol. 3.Subject is virologically seronegative to SARS-CoV-2 infection as confirmed by RT-PCR prior to enrolment. 4.Subject is seronegative to HIV 1 & 2, HBV and HCV infection prior to enrolment. 5.Subject is considered of stable health as judged by the investigator, determined by medical history and physical examination. 6.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. 7.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. 8.Subject agrees not to participate in another clinical trial at any time during the total study period. 9.Subject agrees to refrain from blood donation during the course of the study. 10.Subject agrees to remain in the town where the study centre is located, for the entire duration of the study.

ExclusionCriteria

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 at the time of enrolment. 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: i.severe psychiatric conditions; ii.any bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder); iii.allergic disease or reactions likely to be exacerbated by any component of the study vaccine (BE CORBEVAX vaccine); iv.neurological illness, and any other serious chronic illness requiring hospital specialist supervision. 8.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. i.For corticosteroids, this will mean prednisone ≥0.5 mg/kg/day, or equivalent. ii.Inhaled and topical steroids are allowed. iii.Receipt of prohibited concomitant medication that may jeopardize the safety of the participant or interpretation of the data. 9.Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required). 10.Any medical condition that in the judgment of the investigator would make study participation unsafe. 11.Planned use of any investigational or non-registered product other than the study vaccine during the trial period or 3 months prior to enrolment. 12.Current or planned participation in prophylactic drug trials for the duration of the study. 13.Individuals who are part of the study team or close family members of individuals conducting the study.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	TimePoints
1.Proportion of subjects with solicited adverse reactions/symptoms 2.Proportion of subjects with unsolicited adverse events (AEs) 3.SAEs & MAAE in all subjects.	1.during first 60 minutes of post vaccination and subsequent 7 days. 2.28-day follow-up period after each dose. 3.At 6 and 12months post 2nd dose.
1.Anti-RBD IgG antibodies in terms of ratio of IgG1 to IgG4 anti-RBD titres. 2.Neutralizing antibody titre 3.Immunogenicity in terms of GMC/T 4.Proportion of subjects seroconverted in terms of ≥2-fold & ≥4-fold rise 5.Cell mediated immunity assessment in terms of cytokine expression from stimulated PBMCs (INF-γ, IL-4)	1.at day 42 vs baseline. 2.at baseline and again at day 42. 3.at baseline and again at day 42. 4.in baseline seronegative subjects and ≥2-fold rise in baseline seropositive subjects along with their GMFR at day 42 5.at baseline and at day 42

Secondary Outcome

Outcome	TimePoints
At Phase-II: Anti-RBD IgG concentrations (GMC, Fold Rise, GMFR)	At baseline, day 28, 42 and 56 and at 6 and 12 months post second dose.
Anti-RBD IgG subclass assessment in terms of ratio of IgG1 to IgG4 titres	At day 42 & day 56.
Neutralizing antibody titre	At baseline, day 28, 42, 56 and at 6 and 12 months post second dose.
Cell mediated immunity assessment in terms of	At baseline and at day 42

	cytokine expression from stimulated PBMCs (INF-γ, IL-4)	
	At Phase-III: Proportion of subjects with solicited adverse reactions/symptoms	During first 60 minutes of post vaccination observation period and for subsequent 7 consecutive days
	Proportion of subjects with unsolicited adverse events (AEs)	During the 28-day follow up period after each dose
	SAEs and MAAES	During the entire study period
	Safety follow-up visit	At 6 and12 months post 2nd dose

Target Sample Size	**Total Sample Size=**"1268" **Sample Size from India=**"1268" **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)	07/06/2021
Date of Study Completion (India)	Applicable only for Completed/Terminated trials
Date of First Enrollment (Global)	Date Missing
Date of Study Completion (Global)	Applicable only for Completed/Terminated trials
Estimated Duration of Trial	**Years=**"1" **Months=**"2" **Days=**"0"
Recruitment Status of Trial (Global) Modification(s)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	None
Individual Participant Data (IPD) Sharing Statement	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?** **Response** - NO
Brief Summary	This is a prospective, open-label, single arm, phase II seamlessly followed by Phase III clinical study design to evaluate the immunogenicity and safety of CORBEVAX vaccine for Protection Against COVID-19 Disease When administered to COVID-19-Negative Adult Subjects between18-80 years of age. A total of 1268 male and non-pregnant female adult, from moderate to high-risk population with and without comorbidities will be enrolled across both phases of the study. Subjects must be RT-PCR negative to SARS-CoV-2 antigen. A total of 100 subjects, aged 18 to 55 years, will be enrolled in Phase II for safety assessment and a total of 1168 subjects, aged 18 to 80 years, will be enrolled in Phase III to receive BioE's SARS-CoV-2 vaccine (CORBEVAX). 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.

Close