Clinical Trial Details (PDF Generation Date :- Sun, 01 Oct 2023 04:44:56 GMT)

CTRI Number	CTRI/2021/10/037066 [Registered on: 04/10/2021] - **Trial Registered Prospectively**
Last Modified On	24/03/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Biological E's CORBEVAX vaccine clinical study for protection against Covid-19 disease in children.
Scientific Title of Study	A Prospective, Randomised, Double-blind, Placebo controlled, Phase-II by III Study to Evaluate Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX Vaccine in Children and Adolescents.

Secondary IDs if Any

Secondary ID	Identifier
BECT072/Covid-19-phase-II&III/CTP-01 Ver:1.1 Dated:11.08.21	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 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

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?
Ethics Committee Guru Teg Bahadur Hospital	Approved	06/10/2021	No
Ethics Committee, St. Theresas Hospital	Approved	01/10/2021	No
Ethics Committee-D.Y.Patil Vidyapeeth	Approved	07/12/2021	No
Ethics Committee-Shubham Sudbhawana Super speciality Hospital	Approved	09/10/2021	No
Gillurkar Hospital Ethics Committee	Approved	18/11/2021	No
IEC NIMS University	Approved	04/10/2021	No
IEC Prakhar Hospital Pvt Ltd	Approved	20/10/2021	No
IEC- KLE Academy of Higher Education & Research	Approved	26/10/2021	No
IEC-Mysore Medical College and Research Institute	Approved	08/10/2021	No
Institutional Ethics Committee - Mahatma Gandhi Institute of Medical Sciences	Approved	23/10/2021	No
Institutional Ethics Committee JSS Medical College	Approved	05/10/2021	No
Institutional Ethics Committee- Unique Childrens Hospital Pvt Ltd	Approved	16/12/2021	No

Institutional Ethics Committee- Aakash Healthcare Super Speciality Hospital	Approved	19/11/2021	No
Institutional Ethics Committee- ESIC medical college & Hospital	Approved	16/10/2021	No
Institutional Ethics Committee- Government Medical College and Hospital	Approved	25/10/2021	No
Institutional Ethics Committee- Induss Hospital	Approved	06/11/2021	No
Institutional Ethics Committee- Jawahar Lal Nehru Medical college	Approved	22/11/2021	No
Institutional Ethics Committee- Jeevan Rekha Hospital	Approved	06/11/2021	No
Institutional Human Ethics Committee Chettinad Academy of Research and Education	Approved	09/12/2021	No
Institutional Review Board-Sant Dnyaneshwar Medical Education & Research Centre	Approved	27/10/2021	No
IRB Christian Medical college, Vellore	Approved	30/11/2021	No
Lifepoint Research-Ethics Committee	Approved	09/11/2021	No
Medanta Institutional Ethics Committee	Approved	23/10/2021	No
Penta-Med- Ethics Committee	Approved	12/11/2021	No
Samvedna Hospital Ethics Committee	Approved	15/11/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	01/09/2021

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, Day 28 and booster dose on Day 208.
Comparator Agent	PLACEBO	Dose: 0.5ml, Route of administration: Intramuscular

		injection, Frequency: Two doses at Day 0 and Day 28

Inclusion Criteria

Inclusion Criteria	
Age From	5.00 Year(s)
Age To	18.00 Year(s)
Gender	Both
Details	1. Ability to provide written informed consent (by the parents or legally acceptable/authorized representative (LAR) and assent by the children aged between ?7 to <18 years. 2. Subject, in the opinion of the investigator, has ability to communicate and willingness to comply with the requirements of the protocol. 3. Participants of either gender of age between <18years to ?5 (Participant should be <18 years at the time of Screening of the study). 4. Participants virologically seronegative to SARS-CoV-2 infection by RT-PCR and anti-SARS-CoV-2 antibody prior to enrolment. 5. Participants considered of stable health as judged by the investigator, determined by medical history and physical examination with normal vital signs as defined in the protocol. [Normal vital sign defined as body temperature <100.4ºF prior to enrolment]. 6. Agrees not to participate in another clinical trial at any time during the total study period. 7. Agrees to remain in the town where the study centre is located, for the entire duration of the study. 8. Willing to allow storage and future use of collected biological samples for future research in an anonymised form.

Exclusion Criteria

Exclusion Criteria	
Details	1. History of vaccination with any investigational vaccine against COVID-19 disease; 2. Seropositive to IgG antibodies against SARS CoV-2 3. Living in the same household of any COVID-19 positive person; 4. Use of any investigational or non-registered product other than the study vaccine during the trial period or 3 months prior to enrolment; 5. 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); 6. Current or planned participation in prophylactic drug trials for the duration of the study. 7. Known history of HIV 1 & 2, HBV and HCV infection in participants prior to enrolment.; 8. Body temperature of ?100.4°F (>38.0°C) or symptoms of an acute illness at the time of screening or prior to vaccination; 9. History of severe psychiatric conditions likely to affect participation in the study; 10. History of any bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder); 11. History of allergic disease or reactions likely to be exacerbated by any component of the Biological E's CORBEVAX vaccine formulations; 12. Chronic respiratory disease, including asthma; 13. Chronic cardiovascular disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder and neurological illness; 14. Any other serious chronic illness requiring hospital specialist supervision; 15. 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. For corticosteroids, this will mean prednisolone ?0.5 mg/kg/day, or

	equivalent. Inhaled and topical steroids are allowed; 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. Individuals who are part of the study team or close family members of individuals conducting the study. 19. Anaphylactic reaction following administration of the investigational vaccine.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	On-site computer system
Blinding/Masking	Participant, Investigator, Outcome Assessor and Date-entry Operator Blinded

Primary Outcome

Outcome	Timepoints
Phase II: 1. Occurrence of any adverse reactions. 2.The occurrence of solicited symptoms and their severity. 3. The occurrence of any unsolicited adverse events and their severity. 4. The occurrence and severity of any SAEs or medically attended AEs or AEs of special interest (AESIs). Phase III: 1. Immune response in terms of geometric mean neutralizing titres and their geometric mean fold rise	Phase II: 1. Within 60 minutes of immediate post vaccination period after each dose. 2. 7 consecutive days after each dose. 3.Till 28 days after each post vaccination period. 4. 28 days after each dose. Phase III: 1. from baseline, at day 42.

Secondary Outcome

Outcome	Timepoints
Occurrence and severity of any adverse reactions	Within 60 minutes of immediate post vaccination period
Occurrence and severity of solicited symptoms	Within 7 consecutive days after each dose
Occurrence and severity of any unsolicited adverse events	After each dose till 28 days post vaccination period
Occurrence and severity of any SAEs or medically attended AEs or AEs of special interest (AESIs) in all study participants	Up to 28 days post 2nd dose
Immune response in terms of Geometric mean concentrations and GMFR.	From baseline at day 42
Seroconversion rates in terms of proportion of subjects with ?4-fold increase	From baseline at day 42

Target Sample Size	**Total Sample Size=**624 **Sample Size from India=**624 **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)	11/10/2021
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 phase-II seamlessly followed by phase-III double-blind randomised study to assess safety, tolerability, reactogenicity and immunogenicity of the Biological E's CORBEVAX vaccine in children and adolescents aged between <18 years - ?5 years with placebo as a control. The enrolment of subjects will be done in an age stepdown approach with two age subgroups under each treatment arm viz. age subgroup-1 with subjects <18 to ?12 years of age and age subgroup-2 with subjects <12 to ?5 years of age. There would be two treatment arms/groups in this study i.e Test Vaccine Group and Placebo Group. All eligible subjects will be randomised by treatment planned and by age into respective arms. 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.