



Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 18:15:08 GMT)

CTRI Number	CTRI/2021/06/034014 [Registered on: 04/06/2021] - Trial Registered Prospectively		
Last Modified On	06/01/2022		
Post Graduate Thesis	No		
Type of Trial	Interventional		
Type of Study	Vaccine Biological Preventive		
Study Design	Single Arm Study		
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.		
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)	Details of Principal Investigator		
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	Affiliation	Biological E.Limited	
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	Details Contact Person (Scientific Query)	Details Contact Person (Scientific Query)	
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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
Dr Ravi B Nagarajaiah	Adichunchanagiri Hospital & Research Centre	Dept of General Medicine, 1st floor, B G Nagara Nagamangala Taluk, Mandya-571448 Mandya KARNATAKA	9448323893 ravibn972@yahoo.com
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Dr Anil Kumar Pandey	ESIC Medical College and Hospital	Room No. 440, 4th Floor, NH-3 behind BK Hospital New Industrial Town-121001 Faridabad HARYANA	7042918222 drpandeyak@yahoo.co.in
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	Sciences & SUM Hospital	community Medicine, 3rd Floor,K-8, Kalinga Nagar, Ghatikia,Bhubaneswar-751003 Baleshwar ORISSA	e.venkata.rao@gmail.com	
Dr Madhav Prabhu	KLES Dr. Prabhakar Kore Hospital and MRC	Department of Medicine, Nehru Nagar,Belgavi-590010 Belgaum KARNATAKA	9738462380 wiseman2380@yahoo.com	
Dr Manish Kumar Jain	Maharaja Agrasen Superspeciality Hospital	Department of Pulmonology, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyanagar-302039 Jaipur RAJASTHAN	9414414834 doctormanishjain2@gmail.com	
Dr Pajanivel Ranganadin	Mahatma Gandhi Medical College& Research Institute	1st floor, I block, Pondicherry-Cuddalore Road, ECRMain Road, Pillayarkuppam-607402, Pondicherry PONDICHERRY	9443493122 pajanivelr@mgmcri.ac.in	
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Dr A Venkateshwar Rao	St.Theresas Hospital	Room No. 5, Department of Medicine, Sanathnagar-500018 Hyderabad TELANGANA	9440040662 drvenkateshwarraoavula@gmail.com	
Dr Sandeep Jain	Tagore Hospital and Research Centre	Ground floor,Tagore Lane, Sector-7, Shipra Path, Madhyam Marg, Mansarovar-302020 Jaipur RAJASTHAN	9414069583 drsandeepjain@yahoo.co.in	
Details of Ethics Committee	Name of Committee	Approval Status	Date of Approval	Is Independent Ethics



			Committee?
Ethical Committee, Mahatma Gandhi Medical College and Research Institute	Approved	02/08/2021	No
Ethics Committee downtown hospital	Approved	16/08/2021	No
Ethics Committee GSVM Medical College	Approved	08/09/2021	No
Ethics Committee, St. Theresa's Hospital	Approved	07/06/2021	No
Guru Teg Bahadur Hospital Ethics Committee	Approved	03/06/2021	No
IEC ESIC Medical College and Hospital,	Approved	08/06/2021	No
IEC Prakhar Hospital Pvt Ltd	Approved	04/06/2021	No
IEC, All India Institute of Medical Sciences, Patna	Approved	09/06/2021	No
IEC, Maharaja Agrasen Hospital	Approved	06/06/2021	No
Institutional Ethics Committee of AH and RC Adichunchanagiri Hospital and Research Center	Approved	24/06/2021	No
Institutional Ethics Committee, IMS & SUM Hospital	Approved	07/07/2021	No
Institutional Ethics committee, KLES Dr. Prabhakar Kore Hospital	Approved	17/06/2021	No
Institutional Ethics Committee- AIG Hospital	Approved	15/06/2021	No
Pagarav Ethics committee	Approved	17/07/2021	No
Tagore Hospital Ethics Committee	Approved	03/07/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	20/05/2021

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 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

Inclusion Criteria



Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	<p>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.

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Exclusion Criteria

Exclusion Criteria	
Details	<p>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</p>



	<p>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.</p> <p>i. For corticosteroids, this will mean prednisone 0.5 mg/kg/day, or equivalent.</p> <p>ii. Inhaled and topical steroids are allowed.</p> <p>iii. Receipt of prohibited concomitant medication that may jeopardize the safety of the participant or interpretation of the data.</p> <p>9. Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).</p> <p>10. Any medical condition that in the judgment of the investigator would make study participation unsafe.</p> <p>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.</p> <p>12. Current or planned participation in prophylactic drug trials for the duration of the study.</p> <p>13. Individuals who are part of the study team or close family members of individuals conducting the study.</p>
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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 12 months 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-?, 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 cytokine expression from stimulated PBMCs (INF-?, IL-4)	At baseline and at day 42
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 and 12 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 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)	Closed to Recruitment of Participants	
Publication Details	None	
Brief Summary	<p>This is a prospective, open-label, single arm, phase 1 sequentially followed by Phase II 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 between 18-80 years of age.</p> <p>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 I for safety assessment and a total of 1168 subjects, aged 18 to 80 years, will be enrolled in Phase II to assess Baxi's SARS-CoV-2 vaccine (CORBEVAX).</p> <p>The study will be conducted in compliance with GDR 227(5), ICH and Indian good clinical practice guidelines in force at the time of study conduct.</p>	