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

CTRI Number	**CTRI/2020/11/029032** [Registered on: 10/11/2020] **Trial Registered Prospectively**
Last Modified On:	17/11/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Biological E's novel Covid-19 vaccine of SARS-CoV-2 for protection against Covid-19 disease.
Scientific Title of Study	A prospective open label randomised phase-I seamlessly followed by phase-II study to assess the safety, reactogenicity and immunogenicity of Biological E's novel Covid-19 vaccine containing Receptor Binding Domain of SARS-CoV-2 for protection against Covid-19 disease when administered intramuscularly in a two dose schedule (0, 28D) to healthy volunteers.
Trial Acronym	None
Secondary IDs if Any	**Secondary ID** / **Identifier** BECT062/Covid-19-phase-I&II/CTP-01Ver: 1.1 dated:07.10.20 / Protocol Number
Details of Principal Investigator or overall Trial Coordinator (multi-center study)	**Name**: DrSubhash Thuluva **Designation**: Vice President - Clinical Development **Affiliation**: Biological E.Limited **Address**: Clinical affairs & Pharmacovigilance Dept, 2nd floor, Road No.35, Jubilee Hills Hyderabad TELANGANA 500033 India **Phone**: 04071216248 **Fax**: 04027675309 **Email**: subhash.thuluva@biologicale.com
Details of Contact Person Scientific Query	Name: DrSubhash Thuluva **Designation**: Vice President - Clinical Development **Affiliation**: Biological E.Limited **Address**: Clinical affairs & Pharmacovigilance Dept, 2nd floor, Road No.35, Jubilee Hills TELANGANA 500033 India **Phone**: 04071216248

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Details of Contact Person Public Query

Name	DrTSA Kishore
Designation	Associate Vice President
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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 = **5**

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Chandramani Singh	All India Institute of Medical Sciences	Room No. 17 Department of Community & Family Medicine, Aurangabad Road Phulwari Sharif, Patna 801507. Aurangabad BIHAR	09931733280 drcmsingh@aiimspatna.org
Dr Puneet Misra	All India Institute of Medical Sciences	1st Floor, Room No. 14, Department of community Medicine, Ansari Nagar, New Delhi 110029.	09868397372 doctormisra@gmail.com

		South DELHI	
Dr Venugopal	King George Hospital	1st Floor, Room No. 09, Department of Paediatrics, Collectorate Junction, Maharani Peta,530002. Visakhapatnam ANDHRA PRADESH	09866739808 fbnc.amc@gmail.com
Dr A Venkateshwar Rao	St. Theresa s Hospital	1st Floor, Room No. 05, Erragadda Main Road Czech Colony Sanath Nagar-500038 Hyderabad TELANGANA	09440383778 drvenkateshwarraoavula@gmail.com
Dr Shiv Narang	UCMS & Guru Teg Bahadur Hospital,	7th Floor, Room No. 27, Department of General Medicine,Dilshad Garden, Shahdara,110095. North East DELHI	09899838807 shivanarang@gmail.com

Details of Ethics Committee
Modification(s)

No of Ethics Committees= **5**

Name of Committee	Approval Status
Ethics Committee, St. Theresa's Hospital, Hyderabad	Approved
Guru Teg Bahadur Hospital Ethics Committee, Delhi	Submittted/Under Review
IEC, All India Institute of Medical Sciences, Patna	Approved
Institute Ethics Committee, All India Institute of Medical Sciences, New Delhi	Submittted/Under Review
Institutional Ethics Committee, King George Hospital, Visakhapatnam	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 novel Covid-19 vaccine containing Receptor	With four formulations, BECOV2D, BECOV2C,BECOV2B and BECOV2A. Dose: 0.5ml, Route of administration:Intramuscular

	Binding Domain of SARS-CoV-2	injection, Frequency: Two doses at Day 0 and Day 28.
Comparator Agent	None	None

Inclusion Criteria	**Age From**	18.00 Year(s)
	Age To	65.00 Year(s)
	Gender	Both
	Details	1.Ability and willingness to provide written or thumb printed informed consent prior to performing any study specific procedure. 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 between ≥18 to ≤55 years of age at phase-I and ≥18 to ≤65 years of age at phase-II at the time of 1st vaccination. 4.Participants virologically seronegative to SARS-CoV-2 infection by RT-PCR and anti-SARS-CoV-2 antibody prior to enrolment. 5.Participants seronegative to HIV 1 & 2, HBV and HCV infection prior to enrolment. 6.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 signs defined as pulse rate of ≥60 to ≤100 bpm; blood pressure systolic of ≥90 mm Hg and <140 mm Hg; diastolic ≥ 60 mm Hg and <90 mm Hg; body temperature <100.4ºF prior to enrolment]. 7.Female participants of child bearing potential negative to urine pregnancy test 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; 8.Agrees not to participate in another clinical trial at any time during the total study period. 9.Agrees to refrain from blood donation during the course of the study. 10.Agrees to remain in the town where the study centre is located, for the entire duration of the study. 11.Willing to allow storage and future use of collected biological samples for future research in an anonymised form.

ExclusionCriteria	**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.Pregnant women, nursing women or women of childbearing potential who are not actively avoiding pregnancy during clinical trials; 5.Seriously overweight (BMI ≥ 40 Kg/m2); 6.Use of any investigational or non-registered product other than the study vaccine during the trial period or 3 months prior to enrolment; 7.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); 8.Current or planned participation in prophylactic drug trials for the duration of the study. 9.Any clinically significant abnormal haematology and biochemical laboratory parameters tested at screening as judged by the investigator; 10.Body temperature of ≥100.4°F (>38.0°C) or symptoms of an acute illness at the time of screening or prior to vaccination;

	11.History of severe psychiatric conditions likely to affect participation in the study; 12.History of any bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder); 13.History of allergic disease or reactions likely to be exacerbated by any component of the Biological E's four COVID-19 vaccine formulations; 14.Chronic respiratory diseases, including asthma; 15.Chronic cardiovascular disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder and neurological illness; 16.Any other serious chronic illness requiring hospital specialist supervision; 17.Suspected or known current alcohol abuse as defined by an alcohol intake of greater than 42 units every week for at least one year; 18.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 prednisone ≥0.5 mg/kg/day, or equivalent. Inhaled and topical steroids are allowed; 19.Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required); 20.Any medical condition that in the judgment of the investigator would make study participation unsafe. 21.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	Open Label

Primary Outcome

Outcome	TimePoints
Phase-I 1.any adverse reactions 2.any solicited symptoms 3.any unsolicited adverse events 4.Serious and other medically attended adverse events Phase-II 1.Virus neutralizing antibody (NAb) assay against SARS-CoV-2 virus 2.Seroconversion rates in terms of proportion of subjects with ≥4-fold increase in neutralizing antibodies 3.Geometric mean titres and Geometric mean fold rise in neutralizing antibodies	Phase-I 1.within 2 hours of immediate post vaccination period; 2.within 7 consecutive days after each dose captured through subject diary; 3.at 6 months and 12 months post 2nd dose. 4.at 6 months and 12 months post 2nd dose Phase-II 1.at baseline, 28, 42, 56 days and again at 6 months and 12 months post 2nd dose. 2.from baseline 3.from baseline

Secondary Outcome	<table><tr><th>Outcome</th><th>TimePoints</th></tr><tr><td>Phase-I 1.IgG antibodies against SARS-CoV-2 RBD antigen 2.Virus neutralizing antibody (NAb) assay against SARS-CoV-2 virus 3.Interferon-gamma cytokine levels Phase-II 1.any adverse reactions 2.any solicited symptoms 3.any unsolicited adverse events 4.Serious and other medically attended adverse events in all study participants 5.IgG antibodies against SARS-CoV-2 RBD antigen</td><td>Phase-I 1 & 2.at baseline, 28, 42, 56 days and again at 6 months and 12 months post 2nd dose. 3.at baseline and again at Day 56. Phase-II 1.within 2 hours (first 120 min) of immediate post vaccination period; 2.within 7 consecutive days after each dose captured through subject diary; 3.during 28 days after each dose of study vaccination; 4.at 6 months and 12 months post 2nd dose. 5.at baseline, 28, 42, 56 days and again at 6 months and 12 months post 2nd dose</td></tr></table>
Target Sample Size	**Total Sample Size=**"360" **Sample Size from India=**"360" **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 1/ Phase 2
Date of First Enrollment (India)	16/11/2020
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	**Will individual participant data (IPD) be shared publicly (including data dictionaries)?**

(IPD) Sharing Statement	**Response** - NO
Brief Summary	This is a phase-I seamlessly followed by phase-II, open label, randomized trial to assess safety, tolerability, reactogenicity and immunogenicity of the Biological E's 4 candidate vaccine formulations for preventive protection against COVID-19 disease in adult volunteers of either gender between 18-55 years of age in Phase-I and 18-65 years of age in phase-II. A total of 360 subjects of either gender would be enrolled into the study. 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. The aim of this phase-I seamlessly followed by phase-II is to select a preferred vaccine formulation among the 4 candidate formulations based on overall safety and immunogenicity considerations.

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