Clinical Trial Details (PDF Generation Date :- Fri, 24 Sep 2021 04:50:55 GMT)

CTRI Number	CTRI/2020/11/028976 [Registered on: 09/11/2020] - **Trial Registered Prospectively**
Last Modified On	17/03/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Other
Public Title of Study	A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity,and Lot-to-Lot consistency of BBV152, a Whole virion Inactivated Vaccine in Adults greater than or equal to 18 Years of Age.
Scientific Title of Study	An Event-Driven,Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Study to Evaluate the Efficacy, Safety, Immunogenicity,and Lot-to-Lot consistency of BBV152, a Whole virion Inactivated SARS-CoV-2 Vaccine in Adults greater than or equal to 18 Years of Age.

Secondary IDs if Any

Secondary ID	Identifier
BBIL/BBV152-C/2020 Version No: 3.0; Date: 20-10-2020	Protocol Number

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

Details of Principal Investigator	
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Details Contact Person (Scientific Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Indian Council of Medical Research (ICMR), New Delhi

Primary Sponsor

Primary Sponsor Details	
Name	Bharat Biotech International Ltd
Address	Bharat Biotech International Ltd Genome Valley Shameerpet Hyderabad – 500 078 Telagana INDIA
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
The Indian Council of Medical Research ICMR New Delhi	Indian Council of Medical Research V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, India

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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		KARNATAKA	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee of the Prakhar Hospital	Approved	30/11/2020	No
Ethics Committee Sir Ganga Ram Hospital	Approved	10/12/2020	No
Institutional Ethics Committe Aligarh Muslim University UP	Approved	04/11/2020	No
Institutional Ethics Committe, Jeevan Rekha Hospital, belgaum	Approved	30/11/2020	No
Institutional Ethics Committe, Maharaja Agrasen Superspecilaity Hospital, Jaipur	Approved	10/12/2020	No
Institutional Ethics Committee SRM College Hospital and Research Centre Tamil Nadu	Approved	01/12/2020	No
Institutional Ethics Committee All India Institute of Medical Sciences Bihar	Approved	16/11/2020	No
Institutional Ethics Committee All India Institute of Medical Sciences New Delhi	Approved	17/11/2020	No
Institutional ethics committee DIRECTORATE OF PUBLIC HEALTH AND PREVENTIVE MEDICINE,Chennai	Approved	24/11/2020	No
Institutional ethics committee Gmers Ahmedabad	Approved	04/11/2020	No
Institutional Ethics Committee Grant Government Medical College and Sir J.J. Group of Hospitals Maharashtra	Approved	18/11/2020	No
Institutional ethics committee ICMR-National Institute of Cholera and Enteric Diseases Kolkatta,West Bengal	Approved	21/11/2020	No
Institutional Ethics Committee King George Hospital Visakhapatnam	Approved	10/12/2020	No

Institutional Ethics Committee Lokmanya Tilak Municipal Medical College & General Hospital	Approved	27/11/2020	No
Institutional Ethics Committee Mahatma Gandhi Medical College& Research Institute, Pondicherry	Approved	21/11/2020	No
Institutional Ethics Committee Peoples university Bhopal, Madhya Pradesh	Approved	12/11/2020	No
Institutional Ethics Committee Pt BD Shar ma,PGIMS/UHS.Rohta k, Harvana	Approved	09/11/2020	No
Institutional Ethics Committee Rahate Surgical Hospital & ICU Nagpur	Approved	09/11/2020	No
Institutional Ethics Committee Redkar Hospital and Research Centre Oshalbag Village Dhargal, Tai-Pernem. Goa	Approved	06/11/2020	No
Institutional Ethics Committee Vydehi Institute of Medical Sciences and Research Centre Bengaluru, Karnataka	Approved	26/11/2020	No
Institutional Ethics Committee, Guntur Medical College, Government Fever Hospital, Government General Hospital, Gorantla, Guntur	Approved	10/11/2020	No
Institutional Ethics Committee, IMS & SUM Hospital	Approved	04/11/2020	No
NIMS Institutional Ethics Committee, Nizams institute of Medical Sciences, Punjagutta,	Approved	10/11/2020	No
Prakash Medical college Institutional Ethics Committee	Approved	16/12/2020	No
RCSMGMCIEC	Approved	15/12/2020	No
Translational Health Science and Technology Institute(THSTI), ESIC Medical College and	Approved	24/11/2020	No

Hospital Faridabad			

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	23/10/2020

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Active immunization for the prevention of SARS-CoV-2 infection

Intervention / Comparator Agent

Type	Name	Details
Intervention	BBV152B: 6 µg antigen with Algel-IMDG	Whole-Virion Inactivated SARS-CoV-2 vaccine (BBV152) will be administered as a two dose intramuscular injection 28 days apart.
Comparator Agent	Placebo (Phosphate buffered saline with Algel)	Phosphate buffered saline with Alum (without antigen) will be used as the control.will be administered as a two dose intramuscular injection 28 days apart.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Ability to provide written informed consent and availability to fulfill the study requirements. 2. Participants of either gender of aged 18 years and above. 3. Participants with good general health as determined by the discretion of the investigator, or participants with stable medical conditions. A stable medical condition is defined as a disease not requiring significant change in therapy or hospitalization or worsening disease during the 3 months before enrolment. 4. For a female participant of child-bearing potential, planning to avoid becoming pregnant (use of an effective method of contraception or abstinence) from the time of study enrolment until at least eight weeks after the last vaccination. 5. Male subjects of reproductive potential: Use of condoms to ensure effective contraception with the female partner and to refrain from sperm donation from first vaccination until at least 3 months after the last vaccination. 6. Agrees not to participate in another clinical trial at any time during the study period. 7. Agrees not to take any COVID-19 licensed vaccination for the entire duration of the study. 8. Agrees to remain in the study area for the entire duration of the study. 9. Willing to allow storage and future use of biological samples for future research.

Exclusion Criteria

Exclusion Criteria	
Details	1. History of any other COVID-19 investigational or licensed vaccination. 2. Known history of SARS-CoV-2 infection, as declared by the subject. 3. For women, positive urine pregnancy test before the first dose of vaccination, or any time during the study period. 4. Temperature >38.0°C (100.4°F) or symptoms of an acute self-limited illness such as an upper respiratory infection or gastroenteritis within three days prior to each dose of vaccine. 5. Resident of COVID-19 infection in same household. 6. Known case of HIV, hepatitis B, or hepatitis C infection. 7. Receipt of any licensed/experimental vaccine within four weeks before enrolment in this study. 8. Receipt of immunoglobulin or other blood products within the three months before vaccination in this study. 9. Immunosuppression as a result of an underlying illness or treatment with immunosuppressive or cytotoxic drugs, or use of anticancer

	chemotherapy or radiation therapy within the preceding 36 months. 10. Immunoglobulins, anti-cytokine antibodies and blood products within 6 months prior to study vaccination, during and 21 days following last dose of vaccination. 11. Pregnancy, lactation, or willingness/intention to become pregnant during the first 6 months after enrolment. 12. Severe and/or uncontrolled cardiovascular disease, respiratory disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder,, and neurological illness (mild/moderate well-controlled comorbidities are allowed) Re-Vaccination Exclusion Criteria 13. Pregnancy. 14. History of virologically (RT-PCR) confirmed SARS-CoV-2 infection 15. Anaphylactic reaction following administration of the investigational vaccine.

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
To evaluate the efficacy of BBV152B to prevent symptomatic COVID-19(Virologically confirmed-(RT-PCR positive) which include any participant who meets the Case Definitions for Symptomatic Endpoint and Severe Symptomatic COVID-19	Day 42 to Month 12

Secondary Outcome

Outcome	Timepoints
EFFICACY:To evaluate the efficacy of BBV152B to prevent- 1. COVID-19 based on the case definition for the secondary efficacy symptomatic endpoint. 2.COVID-19-Virologically confirmed (RT-PCR positive) severe cases of COVID19. 3.Any severity of COVID-19 by age. 4.Asymptomatic COVID-19. 5.COVID-19 regardless of symptomatology or severity 6.COVID-19 related deaths 7.Symptomatic COVID-19, regardless of the previous infection	1.Day 42 to Month 12 2.Day 42 to Month 12. 3.Day 42 to Month 12 4.Month 2 to Month 12 5.Day 42 to Month 12 6.Day 42 to Month 12 7.Day 42 to Month 12
SAFETY To assess the safety of BBV152B 1.Serious Adverse Events occurring at any time 2.Solicited local and systemic adverse events (AEs). 3.Unsolicited AEs occurring between the vaccination and 28 days after the final vaccination. 4.Immediate AEs with 30 minutes of vaccination 5. Medically attended adverse events (MAAEs) or AEs leading to withdrawal 6.The occurrence of enhanced respiratory disease episodes reported by participant/documented in hospital records 7.AE of Special interest	1.Throughout the study period 2.Within 7 days post each vaccination 3.Till 28 days post second dose vaccination 4. Within 30 minutes post each vaccination 5.Throughout the study period 6.Throughout the study period 7.Throughout the study period
IMMUNOGENECITY To evaluate the immunogenicity of BBV152B 1.Geometric Mean Titer (GMT) of SARS-CoV-2 Specific Neutralizing Antibody (nAb)	1.Month 0 to Month 12 2.Month 0 to Month 12 3.Month 0 to Month 12 4.Month 0 to Month 2

	2.Geometric Mean Fold Rise (GMFR) of SARS-CoV-2 Neutralizing Antibody (nAb). 3.Geometric Mean Titer (GMT) of SARS-CoV-2 S1 protein-specific Binding Antibody (bAb). 4.Lot-to-Lot consistency will be assessed based on the neutralizing titer of the three consistent lots used in the trial
Target Sample Size	**Total Sample Size=**25800 **Sample Size from India=**25800 **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)	11/11/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	NIL
Brief Summary	[illegible]