Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 13:07:45 GMT)

CTRI Number	CTRI/2020/07/026300 [Registered on: 01/07/2020] - **Trial Registered Prospectively**
Last Modified On	17/03/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Volunteers
Scientific Title of Study	An Adaptive, Seamless Phase 1, Followed by Phase 2 Randomized, Double-blind, Multicenter Study to Evaluate the Safety, Reactogenicity, Tolerability and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (BBV152) in Healthy Volunteers

Secondary IDs if Any

Secondary ID	Identifier
BBIL/BBV152-A/2020; Version 3.0; Date 07-07-2020	Protocol Number

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

Details of Principal Investigator	
Name	Dr V Krishna Mohan
Designation	Whole-time Director
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Details Contact Person (Scientific Query)

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Designation	Whole-time Director
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Bharat Biotech International Ltd Genome Valley Shameerpet Hyderabad – 500 078 Telagana INDIA

Primary Sponsor

Primary Sponsor Details	
Name	Bharat Biotech International Limited
Address	Bharat Biotech International Ltd, Medical Affairs department, Genome Valley, Shameerpet, Medchal, TELANGANA - 500078 India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

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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Dr Venkata rao	Institute of Medical Sciences and SUM Hospital	DEPARTMENT OF COMMUNITY MEDICINE, 3rd Floor, K-8, KALINGA NAGAR, GHATIKIA, Jajapur ORISSA	07853889552 e.venkata.rao@gmail.com
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Dr Ajeet Pratap Singh	Rana Hospital and Trauma Center	Room No. 7 Rana Hospital Pvt. Ltd. Rail Vihar Medical College Road Chargawa Gorakhpur UTTAR PRADESH	7652456810 ajeetpsingh1177@gmail.com
Dr Sagar Vivek Redkar	Redkar Hospital and Research Centre	Room No. 11 Mumbai Goa Highway, Oshalbag Village Dhargal, Tal North Goa GOA	07776084679 redkar.research@gmail.com
Dr Satyajit Mohapatra	SRM Hospital & Research center	Department of Pharmacology , SRM Medical College Hospital and Research Centre, Kattankulathur Campus Kancheepuram TAMIL NADU	09791161626 satyajitmp@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee, All India Institute of Medical Sciences, Delhi	Approved	04/07/2020	No
Ethics Committee, Prakhar Hospital Pvt Ltd,Kanpur	Approved	30/06/2020	No
Gillurkar Hospital Ethics Committee, Nagpur	Approved	20/07/2020	No
Institutional Ethics	Approved	11/07/2020	No

Committee, All India Institute of Medical Sciences, Patna			
Institutional Ethics Committee, IMS & SUM Hospital,odissha	Approved	14/07/2020	No
Institutional Ethics Committee, Jeevan Rekha Hospital, Belgavi	Approved	30/06/2020	No
Institutional Ethics Committee, PGIMS, Rohtak	Approved	13/07/2020	No
Institutional Ethics Committee, Rana Hospital Pvt Ltd, Gorakhpur	Approved	30/06/2020	No
Institutional Ethics Committee, SRM College Hospital and Research Centre,Tamil Nadu	Approved	16/07/2020	No
NIMS Institutional Ethics Committee, Hyderabad	Approved	07/07/2020	No
Redkar Hospital and Research Centre Institutional Ethics Committee, Goa	Approved	30/06/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	10/07/2020

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	BBV152A, BBV152B and BBV152C	Whole-Virion Inactivated SARS-CoV-2 vaccine (BBV152) with three formulations, BBV152A, BBV152B and BBV152C. Dose: 0.5ml, Route of administration:Intramuscular injection, Frequency: Two doses at Day 0 and Day 14
Comparator Agent	Placebo	Placebo will be used as a control. Dose: 0.5ml Route of administration:Intramuscular injection, Frequency:Two doses at Day 0 and Day 14

Inclusion Criteria

Inclusion Criteria	
Age From	12.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	Phase 1 1. Ability to provide written informed consent (Audio video consent for vulnerable subjects). 2. Participants of either gender of age between ?18 to ?55 years. 3. Good general health as determined by the discretion of investigator (vital

	signs (heart rate ?60 to?100 bpm; blood pressure systolic ?90 mm Hg and <140 mm Hg; diastolic ? 60 mm Hg and <90 mm Hg; oral temperature <100.4ºF), medical history, and physical examination). 4. Expressed interest and availability to fulfill the study requirements. 5. 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 four weeks after the last vaccination 6. Male subjects of reproductive potential: Use of condoms to ensure effective contraception with the female partner from first vaccination until 3 months after last vaccination 7. Male subjects agree to refrain from sperm donation from the time of first vaccination until 3 months after last vaccination 8. Participants must refrain from blood or plasma donation from the time of first vaccination until 3 months after last vaccination 9. Agrees not to participate in another clinical trial at any time during the study period. 10. Agrees to remain in the study area for the entire duration of the study. 11. Willing to allow storage and future use of biological samples for future research. Phase 2: 1. Ability to provide written informed consent (Audio video consent for vulnerable subjects). 2. Participants of either gender of age between ?12 to ? 65 years. 3. Good general health as determined by the discretion of investigator (vital signs (heart rate ?60 to?100 bpm; blood pressure systolic ?90 mm Hg and <140 mm Hg; diastolic ? 60 mm Hg and <90 mm Hg; oral temperature <100.4ºF), medical history, and physical examination). 4. Expressed interest and availability to fulfill the study requirements. 5. For a female participant of child-bearing potential, avoid becoming pregnant (use of an effective method of contraception or abstinence) from the time of study enrolment until at least four weeks after the last vaccination and agrees not to participate in another clinical trial at any time during the study period. 6. Male subjects of reproductive potential: Use of condoms to ensure effective contraception with the female partner from first vaccination until 3 months after last vaccination 7. Male subjects agree to refrain from sperm donation from the time of first vaccination until 3 months after last vaccination 8. Participants must refrain from blood or plasma donation from the time of first vaccination until 3 months after last vaccination. 9. Agrees to remain in the study area for the entire duration of the study. 10. Willing to allow storage and future use of biological samples for future research.

Exclusion Criteria

Exclusion Criteria	
Details	Phase 2: 1. History of any other COVID-19 investigational vaccination. 2. Unacceptable laboratory abnormality from screening (prior to first vaccination) or safety testing, as listed below [Abnormal Complete Blood Count (CBC), Random blood sugar level, Renal function test (serum urea and Creatinine), liver function tests, urine analysis report, Positive serology for hepatitis C or HIV antibody or hepatitis B surface antigen]. (Subjects will be informed if their results are positive for hepatitis C, HIV 1 & 2 antibody or hepatitis B surface antigen (HBsAg) and will be referred to a primary care provider for follow up of these abnormal laboratory tests.) 3. Confirmed SARS-CoV-2 at the time of screening using RT-PCR and/or ELISA method. 4. Health care workers. 5. For women, a positive serum pregnancy test (during screening

within 45 days of enrolment) or positive urine pregnancy test (within 24 hours of administering each dose of vaccine).
6. 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.
7. Medical problems as a result of alcohol or illicit drug use during the past 12 months.
8. Receipt of an experimental agent (vaccine, drug, device, etc.) within 60 days before enrollment or expects to receive an investigational agent during the study period.
9. Receipt of any licensed vaccine within four weeks before enrolment in this study.
10. Known sensitivity to any ingredient of the study vaccines, or a more severe allergic reaction and history of allergies in the past.
11. Receipt of immunoglobulin or other blood products within the three months prior to vaccination in this study.
12. 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.
13. Long-term use (> 2 weeks) of oral or parenteral steroids (glucocorticoids) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding six months (nasal and topical steroids are allowed).
14. Any history of hereditary angioedema or idiopathic angioedema.
15. Any history of anaphylaxis in relation to vaccination.
16. Any history of albumin-intolerance.
17. Pregnancy, lactation, or willingness/intention to become pregnant during the study.
18. History of any cancer.
19. History of psychiatric severe conditions likely to affect participation in the study.
20. A bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder, or prior history of significant bleeding or bruising following IM injections or venepuncture.
21. Any other serious chronic illness requiring hospital specialist supervision.
22. Chronic respiratory diseases like severe acute respiratory syndrome (SARS), including mild asthma.
23. Chronic cardiovascular disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder, and neurological illness
24. Morbidly obese (BMI?35 kg/m2) or underweight (BMI ?18 kg/m2).
25. Living in the same household of any COVID-19 positive person.
26. Any other condition that in the opinion of the investigator would jeopardize the safety or rights of a volunteer participating in the trial or would render the subject unable to comply with the protocol.
Re-Vaccination Exclusion Criteria
27. Pregnancy.
28. Anaphylactic reaction following administration of the investigational vaccine.
29. Virologically confirmed cases of COVID-19

Phase 2:
1. History of any other COVID-19 investigational vaccination.
2. Confirmed SARS-CoV-2 at the time of screening using RT-PCR and /or ELISA method.
3. Health care workers.
4. Positive urine pregnancy test (within 24 hours of administering each dose of vaccine).

		5. 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. 6. Medical problems as a result of alcohol or illicit drug use during the past 12 months. 7. Receipt of an experimental agent (vaccine, drug, device, etc.) within 60 days before enrolment or expects to receive an investigational agent during the study period. 8. Receipt of any licensed vaccine within four weeks before enrolment in this study. 9. Known sensitivity to any ingredient of the study vaccines, or a more severe allergic reaction and history of allergies in the past. 10. Receipt of immunoglobulin or other blood products within the three months prior to vaccination in this study. 11. 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. 12. Long-term use (> 2 weeks) of oral or parenteral steroids (glucocorticoids) or high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or equivalent) within the preceding six months (nasal and topical steroids are allowed). 13. Any history of hereditary angioedema or idiopathic angioedema. 14. Any history of anaphylaxis in relation to vaccination. 15. Any history of albumin-intolerance. 16. Pregnancy, lactation, or willingness/intention to become pregnant during the study. 17. History of any cancer. 18. History of psychiatric severe conditions likely to affect participation in the study. 19. A bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder, or prior history of significant bleeding or bruising following IM injections or venepuncture. 20. Any other serious chronic illness requiring hospital specialist supervision. 21. Chronic respiratory diseases like severe acute respiratory syndrome (SARS), including mild asthma. 22. Chronic cardiovascular disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder, and neurological illness 23. Morbidly obese (BMI?35 kg/m2) or underweight (BMI ?18 kg/m2). 24. Living in the same household of any COVID-19 positive person. 25. Any other condition that in the opinion of the investigator would jeopardize the safety or rights of a volunteer participating in the trial or would render the subject unable to comply with the protocol. Re-Vaccination Exclusion Criteria 26. Pregnancy. 27. Anaphylactic reaction following administration of the investigational vaccine. 28. Virologically confirmed cases of COVID-19.
Method of Generating Random Sequence	Computer generated randomization	

Method of Concealment	Centralized
Blinding/Masking	Participant, Investigator and Outcome Assessor Blinded

Primary Outcome

Outcome	Timepoints
Phase 1: 1. The occurrence of immediate adverse events within two hours of vaccination 2. The occurrence of adverse events within 7 days of vaccination.3. The occurrence of any adverse events throughout the study duration 4. The occurrence of serious adverse events (SAEs) Phase 2: Primary 1. To evaluate the immunogenicity in terms of GMT and four-fold seroconversion rate amongst the two selected BBV152 vaccine formulations	Phase 1: Occurrence of Adverse events within 2hrs, at Day 7 and through out the study duration Phase 2: Day 0, Day 14, Day 28, Day 42 Day 104 and Day 194 in two cohorts

Secondary Outcome

Outcome	Timepoints
Phase 1 To evaluate the immunogenicity in terms of GMT and four-fold seroconversion rate of neutralizing antibodies (NAbs) across the three formulations of BBV152 in comparison with control group. Phase 2 The occurrence of immediate adverse events within two hours of vaccination.2. The occurrence of adverse events within seven days of vaccination 3. The occurrence of any adverse events throughout the study duration 4. The occurrence of serious adverse events (SAEs).	Phase 1: Day 0, Day 14, Day 28, Day 42 Day 104 and Day 194 in two cohorts. Phase 2: Occurrence of Adverse events within 2hrs, at Day 7 and through out the study duration

Target Sample Size	**Total Sample Size=**1125 **Sample Size from India=**1125 **Final Enrollment numbers achieved (Total)=**755 **Final Enrollment numbers achieved (India)=**755
Phase of Trial	Phase 1/ Phase 2
Date of First Enrollment (India)	13/07/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**3 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	NIL
Brief Summary	This is a phase 1 to be followed by phase 2 randomized, double-blind, multicenter study to evaluate the safety, reactogenicity, tolerability and immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 vaccine (BBV152) in healthy volunteers. The study is designed to evaluate the safety, reactogenicity, tolerability, and immunogenicity of three groups of healthy volunteers who receive two intramuscular doses of BBV152 vaccine formulations. A total sample size of 1125 healthy volunteers, with 375 volunteers in the phase 1 study and 750 volunteers in phase 2 study (4:1 test and control).