

## Clinical Trial Details (PDF Generation Date :- Tue, 19 Oct 2021 13:13:00 GMT)

| | |
|---|---|
| **CTRI Number** | CTRI/2020/09/027674 [Registered on: 08/09/2020] - **Trial Registered Prospectively** |
| **Last Modified On** | 06/05/2021 |
| **Post Graduate Thesis** | No |
| **Type of Trial** | Interventional |
| **Type of Study** | Vaccine |
| **Study Design** | Other |
| **Public Title of Study** | A Phase 1, Followed by a Phase 2, vaccine given Randomly in subjects in different sites to Evaluate the Safety, side effects, and resistance of the Virus Vaccine, BBV152D Administered between the layers of the skin(intradermal) in Healthy Volunteers. |
| **Scientific Title of Study** | An Adaptive, Seamless Phase 1, Followed by a Phase 2, Randomized, Multicenter Study to Evaluate the Safety, Reactogenicity, and Immunogenicity of the Whole Virion Inactivated SARS-CoV- 2 Virus Vaccine, BBV152D Administered Intradermally in Healthy Volunteers. |

**Secondary IDs if Any**

| Secondary ID | Identifier |
|---|---|
| BBIL/BBV152D-B/2020 Version: 3.0; Dated: 17/08/2020 | Protocol Number |

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

| Details of Principal Investigator | |
|---|---|
| **Name** | Dr Krishna Mohan |
| **Designation** | Whole-time Director |
| **Affiliation** | Bharat Biotech International limited |
| **Address** | Genome valley, Shameerpet, Bharat Biotech International Ltd,<br>Medchal TELANGANA 500078 India<br>Medchal<br>TELANGANA<br>500078<br>India |
| **Phone** | 914023480567 |
| **Fax** | 914023480560 |
| **Email** | kmohan@bharatbiotech.com |

**Details Contact Person (Scientific Query)**

| Details Contact Person (Scientific Query) | |
|---|---|
| **Name** | Dr Krishna Mohan |
| **Designation** | Whole-time Director, |
| **Affiliation** | Bharat Biotech International limited |
| **Address** | Bharat Biotech International Ltd, Medical Affairs Department,<br>Genome Valley, Shameerpet<br>Medchal<br>TELANGANA<br>500078<br>India |
| **Phone** | 04023480567 |
| **Fax** | 04023480560 |
| **Email** | kmohan@bharatbiotech.com |

**Details Contact Person (Public Query)**

| Details Contact Person (Public Query) | |
|---|---|
| **Name** | Dr Krishna Mohan |
| **Designation** | Whole-time Director, |
| **Affiliation** | Bharat Biotech International limited |
| **Address** | Bharat Biotech International Ltd, Medical Affairs Department,<br>Genome Valley, Shameerpet,<br>Medchal<br>TELANGANA |

| | |
|---|---|
| | 500078<br>India |
| **Phone** | 04023480567 |
| **Fax** | 04023480560 |
| **Email** | kmohan@bharatbiotech.com |

**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 Genome Valley Shameerpet Hyderabad – 500 078 Telagana INDIA |
| **Type of Sponsor** | Pharmaceutical industry-Indian |

**Details of Secondary Sponsor**

| Name | Address |
|---|---|
| Bharat Biotech International limited | Bharat Biotech International Ltd Genome Valley Shameerpet Hyderabad – 500 078 Telagana INDIA |

**Countries of Recruitment**

| List of Countries |
|---|
| India |

**Sites of Study**

| Name of Principal Investigator | Name of Site | Site Address | Phone/Fax/Email |
|---|---|---|---|
| DrNChandrashekar | AIG Hospitals,Gachibowli,Hyderabad | AIG Hospitals,CLINICAL RESESRACH DEPARTMENT ,FACILITY BLOCK,5TH FLOOR,136,PLOT NO 2/3/4/5 SURVEY ,1Mind space road,gachibowli,Hyderabad,Telangana,500032<br>Hyderabad<br>TELANGANA | 9959421956<br><br>aigindia2044@gmail.com |
| Dr Atul Rajondawar | Meditrina Institute of Medical sciences,Nagpur | 278,Meditrina Institute of Medical sciences,Central Bazar Road,Ramdaspeth,Nagpur<br>Nagpur<br>MAHARASHTRA | 9373215775<br><br>atul.rajkondawar@gmail.com |
| DrSudagar Singh | Sri Ramachandra Medical Centre,Porur | Sri Ramachandra Medical Centre,General Medicine,Porur 600116<br>Chennai<br>TAMIL NADU | 9003178899<br><br>drsingh7071@gmil.com |
| DrA Venkateswar Rao | St. Theresas Hospital,Hyderabad | St. Theresas Hospital,Sanath Nagar,Hyderabad 500018<br>Hyderabad<br>TELANGANA | 9440040662<br><br>drvenkateshwarraoavula@gmail.com |

**Details of Ethics Committee**

| Name of Committee | Approval Status | Date of Approval | Is Independent Ethics Committee? |
|---|---|---|---|
| Ethics Commitee,St | Approved | 04/09/2020 | No |



| | | | |
|---|---|---|---|
| Theresas Hospital,Sanath nagar Hyderabad | | | |
| Institutional Ethics Commitee,Asian Institute of Gastroenterology | Approved | 08/09/2020 | No |
| Institutional Ethics Committee,SRIHER,Tamil nadu | Approved | 05/09/2020 | No |
| Meditrina Institutional ethics committee,278,Meditrina Institute of Medical sciences,Central Bazar Road,Ramdaspeth,Nagpur | Approved | 04/09/2020 | No |

**Regulatory Clearance Status from DCGI**

| Status | Date |
|---|---|
| Approved/Obtained | 04/09/2020 |

**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 | BBV152D | Whole Virion Inactivated SARS-CoV-2 vaccine (BBV152D) dose:0.1 ml route of administration: intradermally , 1 x 0.1 mL for Arm 1 frequency:day 0 and 14. |
| Intervention | BBV152D | Dose :2 x 0.1 mL for arm 2 at day 0 and 14. Route of administration:Intradermal 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** | 1. Ability to provide written informed consent.<br/> 2. Participants of either gender age between ?18 to ?55 years. (Phase 1)<br/> 3. Participants of either gender age between ?12 to ?65 years. (Phase2)<br/> 4. Good general health as determined by the discretion of investigator (vital signs<br/> (Pulse rate ?60 to?100 bpm; blood pressure systolic ?90 mm Hg and <140 mm<br/> Hg; diastolic ? 60 mm Hg and <90 mm Hg; oral temperature <100.4ºF),<br/> medical history, and physical examination).<br/> 5. Expressed interest and availability to fulfil the study requirements.<br/> 6. For a female participant of child-bearing potential, avoid becoming pregnant<br/> (use of an effective method of contraception or abstinence) from the time of<br/> study enrolment until at least 4 weeks after the last vaccination and agrees not<br/> to participate in another clinical trial at any time during the study period.<br/> 7. Sexually active men who are considered sexually fertile must agree to use a<br/> barrier method of contraception and agree to continue the use for at least 3<br/> months following the last vaccination, or have a partner who is |



| | |
|---|---|
| | permanently<br/> sterile or is medically unable to become pregnant.<br/> 8. Male subjects agree to refrain from sperm donation from the time of first<br/> vaccination until 3 months after last vaccination.<br/> 9. Participants must refrain from blood or plasma donation from the time of first<br/> vaccination until 3 months after last vaccination.<br/> 10. Agrees to remain in the study area for the entire duration of the study.<br/> 11. Willing to allow storage and future use of biological samples for future<br/> research.<br/> |

**Exclusion Criteria**

| Exclusion Criteria | |
|---|---|
| **Details** | 1. History of any other COVID-19 investigational vaccination.<br>2. Unacceptable laboratory abnormality from screening (before first vaccination)<br>or safety testing as listed below.<br>? Hematology, Random blood sugar , Renal function test (Blood urea nitrogen<br>(BUN) and Serum creatinine), liver function tests, urine analysis report, Positive serology for hepatitis C, HIV antibody, and hepatitis B surface antigen. (Subjects will<br>be informed if their results are positive for hepatitis C, HIV 1 & 2 antibody and<br>hepatitis B surface antigen (HBsAg) and will be referred to a primary care provider for<br>follow up of these abnormal laboratory tests.)<br>3. Confirmed SARS-CoV-2 at the time of screening using RT-PCR and ELISA.<br>4. Pregnancy, lactation or willingness/intention to become pregnant during the<br>study<br>5. Temperature > 38.0°C (100.4°F) or symptoms of an acute self-limited illness<br>such as an upper respiratory infection or gastroenteritis within 3 days before<br>each dose of vaccine.<br>6. Medical, problems as a result of alcohol or illicit drug use during the past 12<br>months.<br>7. Receipt of an experimental agent (vaccine, drug, device, etc.) within 60 days<br>before enrolment or expects to receive an experimental agent during the study<br>period.<br>8. Known sensitivity to any ingredient of the study vaccines, or a more severe<br>allergic reaction and history of allergies or anaphylaxis concerning vaccination<br>in the past.<br>9. Receipt of immunoglobulin or other blood products or blood transfusions<br>within the 3 months before vaccination in this study.<br>10. Either Immunosuppressant or Immunocompromised status, as a result of an<br>underlying illness or treatment with immunosuppressive or cytotoxic drugs, or<br>use of anticancer chemotherapy or radiation therapy within the preceding 36<br>months.<br>11. Long-term use (> 2 weeks) of oral or parenteral steroids (glucocorticoids), or<br>high-dose inhaled steroids (>800 mcg/day of beclomethasone dipropionate or |



| | |
|---|---|
| | equivalent) within the preceding 6 months (nasal and topical steroids are<br>allowed).<br>12. Any history of hereditary angioedema or idiopathic angioedema.<br>13. History of any cancer.<br>14. History of serious psychiatric conditions likely to affect participation in the<br>study.<br>15. A bleeding disorder (e.g. factor deficiency, coagulopathy, or platelet disorder),<br>or prior history of significant bleeding following venipuncture.<br>16. Any other serious chronic illness requiring hospital specialist supervision.<br>17. Chronic respiratory diseases (SARS), including mild asthma<br>18. Chronic cardiovascular disease, gastrointestinal disease, liver disease, renal<br>disease, an endocrine disorder, and neurological illness<br>19. Morbidly Obese (BMI?35 kg/m2) or underweight (BMI ?18 kg/m2).<br>20. Living in the same household of any COVID-19 positive.<br>21. New onset of fever or a cough or shortness of breath or anosmia/ageusia since<br>May 2020. Should a reliable test become available, these exclusion criteria will<br>be replaced with seropositivity for COVID-19 before enrolment.<br>22. Any other condition that in the opinion of the investigator would jeopardize the<br>safety or rights of a volunteer participating in the trial or would render the<br>subject unable to comply with the protocol.<br><br>Re-Vaccination Exclusion Criteria<br>1. Pregnancy.<br>2. Anaphylactic reaction following administration of the investigational vaccine.<br>3. Virologically confirmed symptomatic/asymptomatic cases of COVID-19<br>(definition of an symptomatic case of COVID-19 would consist of fever<br>+ Positive COVID-19 test) |

| | |
|---|---|
| **Method of Generating Random Sequence** | Computer generated randomization |
| **Method of Concealment** | Centralized |
| **Blinding/Masking** | Not Applicable |

**Primary Outcome**

| Outcome | Timepoints |
|---|---|
| Phase 1<br>1. The occurrence of immediate adverse events within two hours of vaccination.<br>2. The occurrence of adverse events within seven days .<br>3. The occurrence of any adverse events throughout the study duration<br>4. The occurrence of serious adverse events (SAEs).<br><br>Phase 2<br>1. To evaluate the immunogenicity in terms of four-fold seroconversion rate of SARSCoV-2 virus neutralizing antibodies across the two | Phase 1<br><br>1.Time Frame: 2 hours.<br>2.Time Frame: 7 days<br>3. Time Frame: throughout the study duration<br>4.Time Frame: throughout the study duration.<br><br>Phase 2<br>baseline to day 0, 14, 28, 42, 104 and 194. |



| | |
|---|---|
| | dosage strengths of BBV152D. |

**Secondary Outcome**

| Outcome | Timepoints |
|---|---|
| Phase 1<br>1. To evaluate the immunogenicity in terms of four-fold seroconversion rate across the two dosage strengths of BBV152D.<br>Phase 2:<br>The occurrence of adverse or serious adeverse events | Phase 1<br>baseline to day 14, 28,42, 104 and 194.<br><br>Phase 2<br>2hrs after vaccination,7 days post vaccination,through out study duration. |

| | |
|---|---|
| **Target Sample Size** | **Total Sample Size=**124<br>**Sample Size from India=**124<br>**Final Enrollment numbers achieved (Total)=**0<br>**Final Enrollment numbers achieved (India)=**145 |
| **Phase of Trial** | Phase 1/ Phase 2 |
| **Date of First Enrollment (India)** | 08/09/2020 |
| **Date of First Enrollment (Global)** | No Date Specified |
| **Estimated Duration of Trial** | **Years=**0<br>**Months=**8<br>**Days=**0 |
| **Recruitment Status of Trial (Global)** | Not Applicable |
| **Recruitment Status of Trial (India)** | Completed |
| **Publication Details** | Not applicable |
| **Brief Summary** | This is an adaptive, seamless phase 1, followed by phase 2 randomized, multicenter study to evaluate the safety, reactogenicity, tolerability, and immunogenicity of the Whole Virion Inactivated SARS-CoV-2<br><br>vaccine (BBV152D) in healthy volunteers.<br><br>The study is designed to evaluate the safety, reactogenicity, tolerability, and immunogenicity of healthy volunteers.<br><br>Phase 1<br><br>A total of 24 subjects age between ?18 to ?55 will be enrolled in Phase 1 and is divided into two arms based on the dosage concentration, in Arm 1 subjects will receive 1 x 0.1 mL of BBV152D vaccine<br><br>formulation, in Arm 2 subjects will receive 2 x 0.1 mL of BBV152D vaccine formulation, based on the randomization. Two doses will be administered 14 days apart in healthy volunteers aged 18-55 years.<br><br>Three days after completion of an first dose of vaccine in Arm 1 subjects, a Data Safety Monitoring Board (DSMB), composed of independent subject experts will review safety data till three day of post vaccination<br><br>based on their review and suggestions further enrolment will be continued. A second DSMB meeting will be conducted up on completion of day 6 for Arm 1 and day 3 for Arm 2<br><br>subjects and based on review and suggestions of DSMB phase 2 study will be initiated. |



Phase 2:

A total of 100 healthy subjects ages between ?12 to ?65 years will be enrolled in the phase 2 study, is

divided in to 2 arms based on the dosage concentration and vaccine formulation. Arm 1 subjects will

receive 1 x 0.1 mL of BBV152D vaccine formulation, in Arm 2 subjects will receive 2 x 0.1 mL of

BBV152D vaccine formulation on day 0 and day 14.

A final DSMB meeting will be conducted on completion of day 42 of Phase 2 study

and based on the review, an interim report will be prepared and will be submitted to the

Central Drugs Standard Control Organization (CDSCO), India. The final report will be

prepared and submitted to CDSCO after completion of day 194 of all the subjects

which contains a detailed analysis of the primary and secondary objectives of all visits