Clinical Trial Details (PDF Generation Date :- Wed, 07 Jun 2023 18:10:35 GMT)

CTRI Number	CTRI/2022/02/040065 [Registered on: 07/02/2022] - **Trial Registered Prospectively**
Last Modified On	26/05/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Other
Public Title of Study	Intra-Nasal Covid-19 vaccine Phase-III study in Healthy Volunteers
Scientific Title of Study	A Phase III randomized open label multi-center study to compare immunogenicity and safety of BBV154 with COVAXIN®, and to assess Lot to Lot Consistency of BBV154 in Healthy Volunteers

Secondary IDs if Any

Secondary ID	Identifier
BBIL/BBV154-III/2022, Version No: 2.0; Date: 15-03-2022	Protocol Number

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

Details of Principal Investigator	
Name	Dr Krishna Mohan
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Details Contact Person (Scientific Query)

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Email	kmohan@bharatbiotech.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Bharat Biotech International Limited Genome valley Shameerpet Hyderabad

Primary Sponsor

Primary Sponsor Details	
Name	Bharat Biotech International Limited
Address	Genome valley, Shameerpet Hyderabad
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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		Dhargal, Taluka pemam, North Goa 403513 North Goa GOA	redkar.research@gmail.com
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee Prakhar Hospital Kanpur	Approved	05/02/2022	No
Institutional Ethics Committee, Datta Meghe Medical Sciences, Wardha	Approved	13/04/2022	No
Ethics Committe, Redkar Goa	Approved	05/04/2022	No
Institutional Ethics Commiittee Aatman Hospital	Approved	05/04/2022	No
Institutional Ethics Commiittee All India Institute of Medical Sciences Patna	Approved	05/04/2022	No
Institutional Ethics Committe, Maharaja Agrasen Hospital, Jaipur	Approved	07/04/2022	No
Institutional Ethics Committe, Malla Reddy College for Women, Hyderabad	Approved	12/04/2022	No
Institutional Ethics Committe, Rajarajeshwari Medical college an Hospital, bangalore	Approved	11/04/2022	No
Institutional Ethics Committee Jeevan Rekha Hospital Belgavi	Approved	05/02/2022	No
Institutional Ethics Committee PGIMS Rohtak	Approved	28/02/2022	No
Institutional Ethics Committee Rana Hospital Gorakhpur	Approved	04/04/2022	No
Institutional Ethics Committee, VIMS Vizag	Approved	11/04/2022	No
NIMS Institutional	Approved	06/05/2022	No

Ethics Committee			
O and P Institutional Ethics Committee, Pune	Approved	13/04/2022	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	27/01/2022

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy Volunteers

Intervention / Comparator Agent

Type	Name	Details
Intervention	BBV154 INTRANASAL VACCINE	Replication deficient Adenoviral vector-based (expressing a stabilized spike protein) SARS-CoV-2 vaccine (BBV154) administered 0.5ml of vaccine on day 0 and day 28 via intra-nasal route using a dropper
Comparator Agent	COVAXIN®	Whole-Virion Inactivated SARS-CoV-2 vaccine (COVAXIN®) will be administered at day 0 and day 28 via intramuscular route.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Ability to provide written informed consent. 2. Participants of either gender of age ?18 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 mmHg; diastolic ? 60 mm Hg and <90 mm Hg; oral temperature <100.4ºF), medical history, and physical examination). 4. Expressed interest and availability to fulfil 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. Participants must refrain from blood/plasma or any other bodily fluid donation from the time of first vaccination until 3 months after last vaccination 8. Agrees not to participate in another clinical trial at any time during the study period. 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	1. History of any other COVID-19 investigational/or licensed vaccination. 2. For women of child bearing potential, 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). 3. Temperature >38.0°C (100.4°F) or symptoms of an acute self limiting illness

	such as an upper respiratory infection or gastroenteritis within three days prior to each dose of vaccine. 4. Medical problems because of alcohol or illicit drug use during the past 12 months. 5. 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. 6. Receipt of any licensed vaccine within four weeks before enrolment in this study. 7. Known sensitivity to any ingredient of the study vaccines, or a more severe allergic reaction and history of allergies in the past. 8. Receipt of immunoglobulin or other blood products within the three months prior to 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. 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). 11. Any history of anaphylaxis in relation to vaccination. 12. History of any cancer. 13. History of severe psychiatric conditions likely to affect participation in the study. 14. A bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder, or prior history of significant bleeding or bruising following IM injections or venepuncture). 15. Any other serious chronic illness requiring immediate hospital specialist supervision. 16. 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

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Centralized
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
1. Geometric mean titres (GMTs) of Serum neutralising antibody titer (NAb's) by neutralizing antibody assays. 2.The occurrence of solicited adverse	1. day 0, 28, 42, 90 and 180. 2.7 days. 3. Through out the study 4. Up to day 42 from 1st dose of vaccination

	events. 3. The occurrence of serious adverse events (SAEs) 4. The occurrence of any unsolicited adverse events

Secondary Outcome

Outcome	Timepoints
1. Geometric mean titers of salivary IgA, Serum IgA and IgG binding antibody titer by ELISA assays. 2. Geometric mean titers of Serum neutralizing antibody titer by neutralizing antibody assays. 3. The occurrence of adverse event of special interest (AESI). 4. Vaccine-induced cell mediated immunogenicity and antigen specific T-cell and B-cell responses. 5. The occurrence of the vaccine induced thrombosis and thrombocytopenia in participants reporting the respective symptoms and signs.	1. Day 0, 28, 42, 90 and 180 2. Day 0, 28 and 42 3. Throughout the study

Target Sample Size	**Total Sample Size=**3160 **Sample Size from India=**3160 **Final Enrollment numbers achieved (Total)=**0 **Final Enrollment numbers achieved (India)=**3160
Phase of Trial	Phase 3
Date of First Enrollment (India)	15/02/2022
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**9 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Not Applicable
Brief Summary	A Phase III randomized open label multi-center study to compare immunogenicity and safety of BBV154 with COVAXIN®, and to assess Lot to Lot Consistency of BBV154 in Healthy Volunteers. **Study Design:** A total sample size of 3160 healthy volunteer's age's ?18 years will be recruited in this study. **Group 1 (BBV154)**: In this group, 3000 participants will be recruited, randomized in 1:1:1 ratio receive 3 consecutive lots (Lot 1: 1000, Lot 2: 1000, Lot 3: 1000) of the BBV154 vaccine (0.5 mL each dose) on day 0 and day 28 via intranasal route. **Group 2 (COVAXIN®):** In this group, 160 participants will be recruited and administered with COVAXIN® vaccine on day 0 and on day 28 via intramuscular route.