Clinical Trial Details (PDF Generation Date :- Tue, 27 Jul 2021 09:12:09 GMT)

CTRI Number	CTRI/2021/05/033752 [Registered on: 24/05/2021] - **Trial Registered Prospectively**
Last Modified On	11/06/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Other
Public Title of Study	COVAXIN® in paediatric study
Scientific Title of Study	A Phase II/III, Open Label, Multicenter Study to Evaluate the Safety, Reactogenicity and Immunogenicity of the Whole-Virion Inactivated SARS-CoV-2 Vaccine (COVAXIN®) in Healthy Volunteers ages ?18 to ? 2 Years

Secondary IDs if Any

Secondary ID	Identifier
BBIL/BBV152/2021 version 2.0 dated 17.04.2021	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
Affiliation	Bharat Biotech International Limited
Address	Bharat Biotech International Limited Genome valley Shameerpet Hyderabad Hyderabad TELANGANA 500 078 India
Phone	914023480567
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Email	kmohan@bharatbiotech.com

Details Contact Person (Scientific Query)

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Name	Dr V Krishna Mohan
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Affiliation	Bharat Biotech International Limited
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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
Bharat Biotech International Limited	Genome valley Shameerpet Hyderabad

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Chnadramani SIngh	All India Institute of Medical Sciences Patna	Room No 105 Type 4 Block 2 Department of Paediatrics Aurangabad Road Phulwari Sharif Patna BIHAR	9931733280 cmaiims57@gmail.com
Dr Sanjay Kumar Rai	All India Institute of Medical Scienecs Delhi	Department of center for community medicine Room no 29 Old OT block, AIIMS News Delhi New Delhi DELHI	9868397358 drsanjay.aiims@gmail.com
Dr Prashanth	Cheluvambha Hospital Mysore Medical College and Research Institution	Department of Paediatrics Ground Floor, Room no 101, Irwin Road, Mysore Mysore KARNATAKA	9606352062 drsp2013@rediffmail.com
Dr Vasant Khalatkar	Meditrina Institute of Medical Sciences	2nd floor Department of paediatrics Meditrina Institute of Medical Sciences 278 Central Bazar road Ramdapeth Nagpur 440010 Nagpur MAHARASHTRA	9823044438 7122740600 vasant.khalatkar@gmail.com
Dr Virendra Nath Tripathy	Prakhar Hopsital Pvt Ltd	3rd Floor, Clinical Research Department, Room No 301, Arya Nagar, Kanpur Kanpur Nagar UTTAR PRADESH	9415050777 dr.vntripathicr@gmail.com
Dr Mirza Nizam Baig	Pranam Hospitals Hyderabad	3rd floor, Clinical Research Department, Room no: 306, Madinaguda, Hyderabad	9949389002 drmnb007@yahoo.co.in

		Hyderabad TELANGANA	

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committe, Prakhar Hospital	Approved	17/05/2021	No
Institute Ethics Committee All India Institute of Medical Sciences, New Delhi	Approved	04/06/2021	No
Institutional Ethics Committe, All India Institute of Medical Sciences, Patna	Approved	19/05/2021	No
Institutional Ethics Committe, Mysore Medical College, Mysore	Approved	18/05/2021	No
Institutional Ethics Committe, Pranaam Hospitals	Approved	24/05/2021	No
Meditrina Institute Ethics committee	Approved	21/05/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	12/05/2021

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Healthy

Intervention / Comparator Agent

Type	Name	Details
Intervention	BBV152	0.5 ml administered intramuscular at day 0 and day 28
Comparator Agent	NA	NA

Inclusion Criteria

Inclusion Criteria	
Age From	2.00 Year(s)
Age To	18.00 Year(s)
Gender	Both
Details	1. Ability to provide written informed consent (by the parents or legally acceptable/authorized representative (LAR) and assent by the children (verbal/oral assent for the children of age between 7-12 years, and written assent for the children of age between >12 to 18 years), and Audio video consent for all participants. 2. Participants of either gender of age between ?2 to ?18years (Participant should be ?18 years at the time of Screening of the study). 3. Good general health as determined by the discretion of investigator. 4. Expressed interest and availability to fulfill the study requirements. 5. Agrees not to participate in another clinical trial at any time during the study period. 6. Agrees to remain in the study area for the entire duration of the study. 7. 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 vaccination. 2. Confirmed SARS-CoV-2 at the time of screening using RT-PCR and ELISA method.

	3. 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. 4. 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. 5. Receipt of any licensed vaccine within four weeks before enrolment in this study. 6. Known sensitivity to any ingredient of the study vaccines, or a more severe allergic reaction and history of allergies in the past. 7. Receipt of immunoglobulin or other blood products within the three months prior to vaccination in this study. 8. 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. 9. 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). 10. Any history of hereditary angioedema or idiopathic angioedema. 11. Any history of anaphylaxis in relation to vaccination. 12. History of congenital diseases. 13. Any history of albumin-intolerance. 14. History of any cancer. 15. History of psychiatric severe conditions likely to affect participation in the study. 16. A bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder, or prior history of significant bleeding or bruising following IM injections or venepuncture. 17. Any other serious chronic illness requiring hospital specialist supervision. 18. Respiratory diseases like severe acute respiratory syndrome (SARS), including mild- moderate asthma. 19. Chronic cardiovascular disease, gastrointestinal disease, liver disease, renal disease, endocrine disorder, and neurological illness. 20. History of SARS-CoV-2 infection or known close contact with anyone with laboratory-confirmed SARS-CoV-2 infection or COVID-19 within 2 weeks prior to vaccine administration. 21. 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 22. Anaphylactic reaction following administration of the investigational vaccine. 23. Virologically confirmed cases of COVID-19 through nucleic acid tests

Method of Generating Random Sequence	Not Applicable
Method of Concealment	An Open list of random numbers
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
1 Occurrence of immediate adverse events within two hours of vaccination 2 Occurrence of solicited local and systemic adverse events within 7 days after vaccination and unsolicited adverse events within 28 days after vaccination.	Day 28±2, 56±7, 118±7 and 208±7

	3 Occurrence of Serious Adverse Events throughout the study duration. 4 Occurrence of Adverse Events of Special Interest (AESI) throughout the study duration 5 To evaluate the GMTs and seroconversion of COVAXIN®

Secondary Outcome

Outcome	Timepoints
• To evaluate the GMT and four-fold seroconversion rate of binding antibodies (bAb's) IgG against spike protein (S1 and RBD) and Nucleocapsid (N) protein in all three groups from baseline to day 28, 56, 118 and 208. [Time Frame: Baseline to Day 28±2, 56±7, 118±7 and 208±7].	Day 28±2, 56±7, 118±7 and 208±7

Target Sample Size	**Total Sample Size=**525 **Sample Size from India=**525 **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 2/ Phase 3
Date of First Enrollment (India)	26/05/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	no
Brief Summary	The study is designed to evaluate the safety, reactogenicity and immunogenicity of three groups ages ?18 - >12, ?12 ->6, ? 6 - ≥2 years of healthy volunteers who receive two doses of the whole virion inactivated SARS-CoV-2 virus vaccine (COVAXIN®) 28 days apart. Participants will be recruited in age de-escalatory manner as follows: Group I: Children of age ?18 - >12 years (n=175). Group II: Children of age ?12 - >6 years (n=175). Group III: Children of age ? 6 - ? 2 years (n=175). Group1: A total of 175 healthy volunteers ages ?18->12, years will be enrolled in this group and will receive two doses of COVAXIN® vaccine through intramuscular route on Day 0 and Day 28+2. Group 2: A total of 175 healthy volunteers ages ?12- >6, years will be enrolled in this group and will receive two doses of COVAXIN® vaccine through intramuscular route on Day 0 and Day 28+2.

Group 3: A total of 175 healthy volunteers ages ? 6 - ≥ 2 years will be enrolled in this group and will receive two doses of COVAXIN® vaccine through intramuscular route on Day 0 and Day 28+2.