Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 11:27:38 GMT)

CTRI Number	CTRI/2022/04/042017 [Registered on: 21/04/2022] - **Trial Registered Prospectively**
Last Modified On	30/03/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Active Controlled Trial
Public Title of Study	Study to check the effect of Covovax vaccine when administered as booster dose in adults in India who have already received two doses of COVID-19 vaccines
Scientific Title of Study	A phase 3, observer-blind, randomized, controlled study to evaluate the safety and immunogenicity of a booster dose of COVOVAX in Indian adults who have received primary vaccination against COVID-19

Secondary IDs if Any

Secondary ID	Identifier
COVOVAX-Booster Version No. 4.0 Dated 21 April 2022	Protocol Number

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

Details of Principal Investigator	
Name	
Designation	
Affiliation	
Address	
Phone	
Fax	
Email	

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Designation	Executive Director
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Details Contact Person (Public Query)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Serum Institute of India Private Limited, Pune

Primary Sponsor

Primary Sponsor Details	
Name	Serum Institute of India Private Limited Pune
Address	Serum Institute of India Private Limited 212/2, Hadapsar, Pune – 411028, 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
Dr Hira Lal Bhalla	All India Institute of Medical Sciences, Gorakhpur	Department of Pharmacology, All India Institute of Medical Sciences, Department of Pharmacology, Gorakhpur, Uttar Pradesh - 273008 Gorakhpur UTTAR PRADESH	05512205572 hirabhalla@gmail.com
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Dr S K Raut	Noble Hospitals Pvt. Ltd., Pune	Noble Hospital Pvt. Ltd., 153/A, Magarpatta City Road, Hadapsar, Pune 411013, Maharashtra, India Pune MAHARASHTRA	02066285120 skraut01@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee, Dr. D. Y. Patil Vidyapeeth, Pune	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee Bharati Vidyapeeth Deemed University, Pune	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, HIMSR and Associated HAH Centenary Hospital, New Delhi	Submittted/Under Review	No Date Specified	No

Institutional Ethics Committee, JSS Medical College, Mysore	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Kalinga Institute of Medical Sciences, Bhubneswar	Approved	11/04/2022	No
Institutional Human Ethics Committee All India Institute Of Medical Sciences, Gorakhpur	Submittted/Under Review	No Date Specified	No
KEM Hospital and Research center ethics committee	Approved	09/04/2022	No
Noble Hospital Institutional Ethics Committee, Pune	Submittted/Under Review	No Date Specified	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	22/03/2022

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Prevention of COVID-19 infection

Intervention / Comparator Agent

Type	Name	Details
Intervention	COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant]	Single dose of 0.5 mL contains 5 ?g antigen and 50 ?g Matrix-M1 adjuvant. Dose: 0.5 mL Frequency: Single dose Route of administration: Intramuscular
Comparator Agent	COVISHIELD	COVISHIELD (ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)) One dose (0.5 ml) contains: ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) 5 × 1010 virus particles (vp) Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells. Manufacturer- Serum Institute of India Pvt. Ltd. Dose: 0.5 mL Frequency: Single dose Route of administration: Intramuscular
Comparator Agent	COVAXIN	COVAXIN (Whole Virion Inactivated Coronavirus (SARS-CoV-2) Vaccine) is a white to off white, opalescent suspension free from extraneous particles containing 6 ?g of Whole Virion, Inactivated (SARS-CoV-2) Antigen (strain NIV-2020-770).

			Manufacturer- Bharat Biotech International Limited Dose: 0.5 mL Frequency: Single dose Route of administration: Intramuscular

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Adults aged more than or equal to 18 years of either sex 2. Written informed consent by participants 3. Those who have completed primary COVID-19 vaccination schedule with at least 6 months ago 4. Female participants of childbearing potential must have a negative urine pregnancy test within 24 hours prior to study vaccine administration

Exclusion Criteria

Exclusion Criteria	
Details	1. Acute illness at the time of screening 2. History of laboratory confirmed COVID-19 3. History of allergic reactions after previous vaccinations including primary vaccination for COVID-19 4. Have any bleeding disorder which is considered as a contraindication to intramuscular injection or blood draw 5. Suspected or known current alcohol or drug dependence 6. Chronic administration of immunosuppressant or other immune-modifying drugs within three months prior to the study vaccination or planned use throughout the study period 7. Administration of blood, blood products and/or plasma derivatives or any parenteral immunoglobulin preparation in the past 3 months or planned use throughout the study period 8. Administration of any vaccine within 28 days prior to enrolment in the study or planned administration of any vaccine for until 28 days after study vaccination 9. Prior receipt of a booster dose of COVID-19 vaccine 10. Pregnant or breast-feeding 11. Acute or chronic, clinically significant systemic disorders 12. Any other condition that in the opinion of the investigator would jeopardize the safety or rights of the participant in the study or make it unlikely that the participant could complete the protocol

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

Primary Outcome

Outcome	Timepoints
Anti-S IgG and Neutralizing antibodies	28 days after vaccination

Secondary Outcome

Outcome	Timepoints
Occurrence of solicited local and systemic adverse events (AEs) for 7 days post-vaccination	7 days post-vaccination
Occurrence of unsolicited AEs for 28 days post-vaccination	28 days post-vaccination
Occurrence of SAEs, and adverse events of special interest (AESI) throughout the study duration following vaccination	180 Days Post Vaccination
Anti-S IgG and Neutralizing antibodies	at Day 91 and Day 181

Target Sample Size	**Total Sample Size=**372

	Sample Size from India=372 **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)	25/04/2022
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	NA
Brief Summary	This is a Phase 3, observer-blinded, randomised, active controlled study in adults of more than or equal to 18 years of age in India who have already received primary vaccination against COVID-19 at least 6 months ago (6 months or 180 days from the second dose), to evaluate the immunogenicity and safety of the COVOVAX booster dose in comparison with the control vaccine. A total of 372 eligible participants of ? 18 years of age who have completed primary 2 dose schedule of COVID-19 vaccination at least 6 months ago will be enrolled in this study in 2 cohorts of 186 participants each with 1:1 allocation to COVOVAX or control vaccine. Two cohorts of 186 participants each will be as below: 1. COVISHIELD Prime cohort: Primary vaccination with two doses of COVISHIELD 2. COVAXIN Prime cohort: Primary vaccination with two doses of COVAXIN A total of 372 eligible participants (186 participants from each of 2 cohorts) will be randomized as mentioned above to receive study vaccines. The study vaccines will be injected intramuscularly in the deltoid as a single dose of 0.5 mL on Day 1. The participants will be observed closely for at least 30 minutes following vaccination.