Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 10:14:25 GMT)

CTRI Number	CTRI/2021/02/031554 [Registered on: 25/02/2021] - **Trial Registered Prospectively**
Last Modified On	06/09/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Other
Public Title of Study	The study to check the safety and immune response of (Covid-19 vaccine) COVOVAX in adults (more than 18 years of age) and pediatric population (more than 2 years and less than 17 years of age) in India.
Scientific Title of Study	A phase 2/3, observer-blind, randomized, controlled study to determine the safety and immunogenicity of COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant] in Indian adults aged ?18 years and children aged 2 to 17 years

Secondary IDs if Any

Secondary ID	Identifier
ICMR/SII-COVOVAX Version: 9.0 Dated 26 July 2021	Protocol Number

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

Details of Principal Investigator	
Name	
Designation	
Affiliation	
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Phone	
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Source of Monetary or Material Support

Source of Monetary or Material Support
> Indian Council of Medical Research, New Delhi
> 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 – 411 028, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
Indian Council of Medical Research New Delhi	Indian Council of Medical Research, V. Ramalingaswami Bhawan, P.O. Box No. 4911, Ansari Nagar, New Delhi - 110029, India

Countries of Recruitment

List of Countries
India

Sites of Study

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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Clinical Research Ethics Committee, School of Tropical Medicine, Kolkata	Approved	24/03/2021	No
Ethics Committee, Dr. D. Y. Patil Vidyapeeth, Pune	Approved	25/02/2021	No
Institutional Ethics Committee Amrita Institute of Medical Sciences AIMS-Ponekkara Kochi	Approved	12/03/2021	No
Institutional Ethics committee Bharati Vidyapeeth Deemed University, Pune	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee Christian Medical College & Hospital Ludhiana	Approved	20/03/2021	No
Institutional Ethics Committee Government Medical College and Hospital Nagpur	Approved	26/08/2021	No
Institutional Ethics Committee Intervention Studies, JIPMER, Puducherry	Approved	10/06/2021	No
Institutional Ethics	Approved	19/04/2021	No

Committee of DMIMS, Datta Meghe Institute of Medical Sciences, Sawangi (Meghe) Wardha			
Institutional Ethics Committee Topiwala National Medical College and B.Y.L. Nair Charitable Hospital	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee, Mahatma Gandhi Institute of Medical Sciences, Sewagram	Approved	22/03/2021	No
Institutional Ethics Committee, All India Institute of Medical Sciences (AIIMS), New Delhi	Approved	17/03/2021	No
Institutional Ethics Committee, IMS & SUM Hospital Bhubaneswar	Approved	01/03/2021	No
Institutional Ethics Committee, JSS Medical College, Mysore	Approved	23/02/2021	No
Institutional Ethics Committee, Kalinga Institute of Medical Sciences, Bhubneswar	Approved	12/08/2021	No
Institutional Ethics Committee, KLE University, Belgaum	Approved	19/02/2021	No
Institutional Ethics Committee, Post Graduate Institute of Medical Education and Research-(PGIMER), Chandigarh	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee-1 Seth GS Medical College and KEM Hospital, Mumbai	Submittted/Under Review	No Date Specified	No
Institutional Human Ethics Committee All India Institute Of Medical Sciences, Gorakhpur	Approved	10/03/2021	No
Jamia Hamdard Institutional Ethics Committee, New Delhi	Approved	10/08/2021	No
KEM Hospital Research Centre Ethics Committee, Pune	Approved	01/04/2021	No
KIMS Institutional Ethics Committee, Bangalore	Approved	22/03/2021	No

Noble Hospital Institutional Ethics Committee, Pune	Approved	01/03/2021	No
Sahyadri Hospitals Ltd. Ethics committee, Pune	Approved	08/03/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	29/07/2021

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]	Adult cohort: Phase 2 part: COVOVAX [SARS-CoV-2 recombinant spike protein nanoparticle vaccine (SARS-CoV-2 rS) with Matrix-M1™ adjuvant] Manufacturer: DS manufactured by Novavax and DP (fill finish) by SIIPL. Phase 3 part: COVOVAX; Manufacturer: Serum Institute of India Pvt. Ltd. Pediatric cohort: Test vaccine: COVOVAX; DS and DP manufactured by SIIPL
Comparator Agent	Novavax-SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant	Adult Cohort: Novavax-SARS-CoV-2 Recombinant Spike Protein Nanoparticle Vaccine (SARS-CoV-2 rS) with Matrix-M1™ Adjuvant. DS and DP manufactured by Novavax
Comparator Agent	Placebo	Adult Cohort (Phase 2 part) and Pediatric Cohort: Placebo: 0.9% Normal saline (Sodium chloride) for injection.

Inclusion Criteria

Inclusion Criteria	
Age From	2.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	Adult Cohort: 1. Adults aged more than or equal to 18 years of either sex 2. Written informed consent by participants 3. The participant is resident of the study area and is willing to comply with study protocol requirements 4. Healthy, as determined by medical history and physical examination 5. Sexually active female participants of childbearing potential must have practiced adequate contraception for 28 days prior to study vaccine administration and agree to continue adequate contraception until completion of their Day 36 visit 6. Female participants of childbearing potential must have a negative urine pregnancy test within 24 hours prior to study vaccine Pediatric Cohort: 1. Children aged ? 2 to 17 years of either sex 2. The participant is a resident of the study area and is willing to comply with study protocol requirements, including availability for all scheduled visits of the study 3. Healthy or medically stable, as determined by medical history and physical examination as determined by the investigator. 4. Parent(s) willing and able to

	give written informed consent for 2- to 17 year old children 5. Participants assent (verbal assent for 7- to 11-year old children and written assent for 12- to 17-year old children), as required, prior to study enrolment and to comply with study procedures. 6. Female participants of 12 to 17 years of age who have attained menarche must have a negative urine pregnancy test within 24 hours prior to study vaccine administration

Exclusion Criteria

Exclusion Criteria	
Details	Adult Cohort: 1. Acute illness including COVID-19 with or without fever at the time of study vaccine administration 2. History of laboratory confirmed (by PCR or serology to SARSCoV-2) COVID-19 disease. 3. History of severe allergic reactions after previous vaccinations or hypersensitivity to any component of study vaccines 4. Prior receipt of an investigational or licensed vaccine likely to impact interpretation of the trial data 5. Current or planned participation in prophylactic drug trials for the duration of the study Pediatric Cohort 1. Acute illness including COVID-19 with or without fever at the time of study vaccine administration 2. History of laboratory confirmed (by PCR or serology to SARS-CoV-2) COVID-19 disease 3. History of severe allergic reactions after previous vaccinations or hypersensitivity to any component of study vaccines

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
Occurrence of causally related serious adverse events (SAEs) throughout the study duration following vaccination Immunogenicity Outcomes: a. Ratio of GMEUs of anti-Spike (S) protein IgG and Ratio of GMTs of NAb against SARS CoV-2 Safety Outcomes: a. Occurrence of solicited local and systemic AEs	Throughout the study follow up period 14 days after second vaccination (35 days post first dose vaccination) For 7 days following each dose 35 days post first dose vaccination Throughout the study period following vaccination

Secondary Outcome

Outcome	Timepoints
Occurrence of solicited local and systemic adverse events (AEs)	7 days following each dose
Occurrence of unsolicited adverse events including medically attended adverse events (MAAEs) for	35 days post first dose vaccination
Occurrence of SAEs, related MAAEs, and adverse events of special interest (AESI) which encompasses potential immunemediated medical conditions (PIMMCs) and AESIs relevant to COVID-19	Throughout the study duration following vaccination
GMEUs of anti-S IgG antibodies	Baseline, Day 21, Day 35 and Day 179 post first dose vaccination

Seroconversion for anti-S IgG	Day 21, Day 35 and Day 179 post first dose vaccination
Pediatric cohort: Immunogenicity Outcomes: a. GMEUs of anti-S IgG antibodies and Seroconversion for anti-S IgG	At baseline, 21, 35- and 179-days post first dose vaccination.
b. GMTs of NAb against SARS-CoV-2	At baseline and 35 days post first dose vaccination.

Target Sample Size	**Total Sample Size=**2520 **Sample Size from India=**2520 **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)	26/02/2021
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)	Open to Recruitment
Publication Details	Nil
Brief Summary	This is a Phase 2/3, observer-blinded, randomized, controlled study in adults ? 18 years and children of ? 2 to 17 years of age in India. **Adult Cohort:** A total of 1600 eligible participants of ? 18 years of age will be enrolled in this study. Of these, 460 participants will be part of reactogenicity and immunogenicity cohort. The remaining 1140 participants will be part of safety cohort. All eligible participants (n=1600) will receive two doses of 0.5 mL each of either COVOVAX or Control vaccine (Novavax- SARS-CoV-2 rS with Matrix-M1™ Adjuvant) or Placebo on Day 1 and Day 22 as per randomization. Post vaccination site visits are planned on Day 22, Day 36, Day 85 and Day 180. The study will be conducted in two parts as below: Phase 2 part: Initial 200 participants have been enrolled in the Safety cohort with 3:1 allocation to COVOVAX (n=150) or Placebo (n=50). Phase 3 part: Enrolment of remaining 1400 participants (940 from the Safety cohort and 460 from the reactogenicity and immunogenicity cohort) will be done. **Pediatric cohort:** The study objective in this cohort is to evaluate the safety of COVOVAX in comparison with Placebo; and immunogenicity of COVOVAX in children ? 12 to 17 years of age and ? 2 to 11 years of age in comparison with adult participants (adult participants in the reactogenicity and immunogenicity cohort from COVOVAX group), separately. A total of 920 eligible children of ? 2 years of age will be enrolled in this study. Of these, 460 participants will be of ? 12 to 17 years of age and 460 participants will be of ? 2 to 11 years of age. All eligible participants (n=920) will be randomized in 3:1 ratio to receive two doses of 0.5 mL each

of either COVOVAX or Placebo, respectively, on Day 1 and Day 22.