Clinical Trial Details (PDF Generation Date :- Tue, 24 Nov 2020 05:01:10 GMT)

CTRI Number	CTRI/2020/08/027170 [Registered on: 15/08/2020] - **Trial Registered Prospectively**
Last Modified On	06/11/2020
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group Trial
Public Title of Study	Study to check the safety and immune response of a COVID-19 vaccine in healthy Indian adults.
Scientific Title of Study	A Phase 2/3, Observer-Blind, Randomized, Controlled Study to Determine the Safety and Immunogenicity of Covishield (COVID-19 Vaccine) in Healthy Indian Adults

Secondary IDs if Any

Secondary ID	Identifier
ICMR/SII-COVISHIELD Version 2.0 dtd 29 July 2020	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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Source of Monetary or Material Support

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> Indian Council of Medical Research (ICMR) V. Ramalingaswami Bhawan, P.O. Box No. 4911 Ansari Nagar, New Delhi - 110029, INDIA
> Serum Institute of India Private Limited 212/2, Hadapsar, Pune – 411 028, India

Primary Sponsor

Primary Sponsor Details	
Name	Serum Institute of India Private Limited
Address	212/2, Off Soli Poonawalla Road, Hadapsar, Pune – 411 028, India
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

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

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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Dr Ramkrishnan	Sri Ramchandra Institute of Higher Education and Research, Chennai	Sri Ramchandra Institute of Higher Education and Research, No. 1, Ramchandra Nagar, Porur, Chennai, Tamil	00914445928916 srmcclinicalresearch@gmail.com

		Nadu 600116 Chennai TAMIL NADU	
Dr Renuka Munshi	TN Medical College & BYL Nair Hospital, Mumbai	TN Medical College & BYL Nair Hospital, 5th floor, Department of Clinical Pharmacology, TN Medical College & BYL Nair Hospital, Dr. AL Nair Road, Mumbai Central, Mumbai, Maharashtra 400008 Mumbai MAHARASHTRA	02223027000 renuka.munshi@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Mahatma Gandhi Institute of Medical Sciences, Institutional Ethics Commitee, Sewagram	Approved	27/08/2020	No
Ethics Committee Jehangir Clinical Development Center Pvt.Ltd, Pune	Approved	14/08/2020	No
Ethics Committee Rajendra Memorial Research Institute of Medical Sciences, Patna	Approved	18/08/2020	No
IEC King George Hospital, Visakhapatnam	Approved	17/08/2020	No
Institute Ethics Committee All India Institute of Medical Sciences, New Delhi	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee - TNGMSSH, Chennai	Approved	13/08/2020	No
Institutional Ethics Committee AIIMS Jodhpur	Submittted/Under Review	No Date Specified	No
Institutional Ethics Committee of B. J. Government Medical College and Sassoon General Hospital, Pune	Approved	16/08/2020	No
Institutional Ethics Committee Seth GS Medical College and KEM Hospital, Mumbai.	Approved	05/09/2020	No
Institutional Ethics Committee Sri Ramachandra Institute of Higher Education and Research, Chennai	Approved	26/08/2020	No

Institutional Ethics Committee, BVDU, Pune	Approved	14/08/2020	No
Institutional Ethics Committee, Government Medical College, Nagpur	Approved	23/09/2020	No
Institutional Ethics Committee, JSS Medical College, Mysore	Approved	14/08/2020	No
Institutional Ethics Committee, PGIMER, Chandigarh	Approved	20/08/2020	No
Institutional Ethics Committee, T N Medical College & BYL Nair Hospital, Mumbai	Approved	28/08/2020	No
Institutional Human Ethical Committee, ICMR-RMRC Gorakhpur	Submittted/Under Review	No Date Specified	No
KEM Hospital Research Centre Ethics Committee, Pune	Approved	13/08/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	02/08/2020

Health Condition / Problems Studied

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

Intervention / Comparator Agent

Type	Name	Details
Intervention	Covishield (SII-ChAdOx1 nCoV-19)	Covishield will be administered as 2 dose schedule on Days 1 and 29 as 0.5 ml dose intramuscularly.
Comparator Agent	Oxford/AZ-ChAdOx1 nCoV-19 vaccine	Oxford/AZ-ChAdOx1 nCoV-19 vaccine will be administered as 2 dose schedule on Days 1 and 29 as 0.5 ml dose intramuscularly.
Comparator Agent	Placebo	Placebo will be administered as 2 dose schedule on Days 1 and 29 as 0.5 ml dose intramuscularly.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Healthy 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. 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 with or without fever at the time of study vaccine administration 2. History of laboratory confirmed COVID-19 disease in household contact or close workplace contact 3. IgG seropositivity to SARS-CoV-2 4. History or currently positive for SARS-CoV-2 by RT-PCR 5. History of severe allergic reactions after previous vaccinations or hypersensitivity to any component of study vaccines 6. Any confirmed or suspected condition with impaired/altered function of immune system

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
1. Occurrence of causally related SAEs throughout the study duration following vaccination 2. Ratio of GMTs of anti-S IgG antibodies	1. Throughout the study duration following vaccination 2. 28 days after the second vaccination

Secondary Outcome

Outcome	Timepoints
Occurrence of solicited local and/or systemic adverse events (AEs)	7 days following each vaccination
Occurrence of unsolicited adverse events	28 days following each vaccination
Occurrence of serious adverse events (SAEs)	Throughout the study duration following vaccination

Target Sample Size	**Total Sample Size=**1600 **Sample Size from India=**1600 **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)	24/08/2020
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**0 **Months=**7 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	Nil
Brief Summary	This is a Phase 2/3, observer-blind, randomised, controlled study in healthy adults in India, for comparison of the safety of COVISHIELD with Oxford/AZ-ChAdOx1 nCoV-19 and Placebo, and immunogenicity with Oxford/AZ-ChAdOx1 nCoV-19 in prevention of SARS CoV-2 infection. A total of 1600 eligible participants of more than or equal to 18 years of age will be enrolled the study. Of these 400 participants will be part of immunogenicity cohort and will be randomly assigned in a 3:1 ratio to receive either COVISHIELD or Oxford/AZ-ChAdOx1 nCoV-19, respectively. The remaining 1200 participants from safety cohort will be randomly assigned in a 3:1 ratio to receive either COVISHIELD or Placebo, respectively.