Clinical Trial Details (PDF Generation Date :- Thu, 01 Apr 2021 09:57:20 GMT)

CTRI Number	CTRI/2020/08/027170 [Registered on: 15/08/2020] - **Trial Registered Prospectively**
Last Modified On	28/01/2021
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 4.0 dated 14 Oct 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)	
Name	Dr Prasad Kulkarni
Designation	Medical Director
Affiliation	Serum Institute of India Private Limited
Address	Serum Institute of India Private Limited, 212/2, Hadapsar, Pune – 411 028, India Pune MAHARASHTRA 411028 India
Phone	00912026602949
Fax	00912026993945
Email	drpsk@seruminstitute.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr Prasad Kulkarni
Designation	Medical Director
Affiliation	Serum Institute of India Private Limited
Address	Serum Institute of India Private Limited, 212/2, Hadapsar, Pune – 411 028, India Pune MAHARASHTRA 411028 India
Phone	00912026602949
Fax	00912026993945

Email	drpsk@seruminstitute.com

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
Dr B Devi Madhavi	Andhra Medical College, Visakhapatnam	Department of Community Medicine Andhra Medical College Maharani Peta, Visakhapatnam, Andhra Pradesh 530002, India Visakhapatnam ANDHRA PRADESH	918912712258 drdevimadhavi@rediffmail.com
Dr Muralidhar Tambe	B J Medical College and Sassoon General Hospital, Pune	B J Medical College and Sassoon General Hospital, Jai Prakash Narayan Road, Pune Railway Station, Pune, Maharashtra 411001, India Pune MAHARASHTRA	912026128000 muralidhartambe@gmail.com
Dr Sanjay Lalwani	Bharati Vidyapeeth Deemed University Medical College and Hospital, Pune	Department of Pediatrics Bharati Vidyapeeth Deemed University Medical College and Hospital, Dhankawadi, Pune-Satara Road, Pune-411043, Maharashtra, India Pune MAHARASHTRA	912024364308 researchpedpune@gmail.com
Dr Sushant Meshram	Government Medical College, Nagpur	Department of Respiratory Medicine, Government Medical College, Near Hanuman Nagar, Nagpur, Maharashtra 440009 Nagpur MAHARASHTRA	917122744671 drsushant.in@gmail.com
Dr T S Selvavinayagam	Institute of Community Medicine, Madras	Institute of Community Medicine, Madras	914425305000

		Medical College, Old Central Jail Campus, Park Town, Chennai-600 003, Tamil Nadu, India Chennai TAMIL NADU	drsvinayagam@gmail.com
Dr Kiranjit Singh	Jehangir Hospital, Pune	Jehangir Clinical Development Center, Jehangir Hospital premises, 32 Sassoon Road, Pune 411 001, Maharashtra, India Pune MAHARASHTRA	912066819999 startup@jcdc.co.in
Dr Praveen Kulkarni	JSS Academy of Higher Education and Research, Mysore	Department of Community Medicine, JSS Academy of Higher Education and Research Bannimantap Road, Sri Shivarathreeshwara Nagara, Bannimantap A Layout, Bannimantap, Mysore, Karnataka 570015, India Mysore KARNATAKA	918212548416 prakulfi@gmail.com
Dr Ashish Bavdekar	KEM Hospital Research Centre, Vadu	Department of Paediatrics, KEM Hospital Research Centre Vadu Rural Health Program, Vadu Budruk, Taluka Shirur, Pune - 412216, Maharashtra, India Pune MAHARASHTRA	020-66037342 a.bavdekar@kemhrcpune.org
Dr B S Garg	Mahatma Gandhi Institute of Medical Sciences, Sewagram	Department of Community Medicine, Dr Sushila Nair School of Public Health Mahatma Gandhi Institute of Medical Sciences, Sewagram, Wardha, Maharashtra 442102 Wardha MAHARASHTRA	917152284341 bsgarg@mgims.ac.in
Dr Madhu Gupta	Post Graduate Institute of Medical Education & Research (PGIMER)	Department of Community Medicine and School of Public Health, Post Graduate Institute of Medical Education & Research (PGIMER), Sector -12, Chandigarh- 160012 Punjab, India Chandigarh CHANDIGARH	911722755223 madhugupta21@gmail.com

Dr Krishna Pandey	Rajendra Memorial Research Institute of Medical Sciences, Patna	Rajendra Memorial Research Institute of Medical Sciences (Indian Council of Medical Research) Department of Health Research, Ministry of Health & Family Welfare, Govt of India, Agamkuan, Patna-800007, Bihar, India Patna BIHAR	916122245744 drkrishnapandey@yahoo.com
Dr Nithya Gogtay	Seth G. S. Medical College and KEM Hospital, Mumbai	Department of Clinical Pharmacology, Seth G. S. Medical College and KEM Hospital Acharya Donde Marg, Parel East, Parel, Mumbai, Maharashtra 400012, India Mumbai MAHARASHTRA	00912224133767 njgogtay@hotmail.com
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 Nadu 600116 Chennai TAMIL NADU	00914445928916 srmcclinicalresearch@gmail.com
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	26/10/2020	No
Ethics Committee Jehangir Clinical Development Center Pvt.Ltd, Pune	Approved	22/10/2020	No
Ethics Committee Rajendra Memorial Research Institute of Medical Sciences,	Approved	29/10/2020	No

Patna			
IEC King George Hospital, Visakhapatnam	Approved	28/10/2020	No
Institutional Ethics Committee - TNGMSSH, Chennai	Approved	13/08/2020	No
Institutional Ethics Committee of B. J. Government Medical College and Sassoon General Hospital, Pune	Approved	26/10/2020	No
Institutional Ethics Committee Seth GS Medical College and KEM Hospital, Mumbai.	Approved	28/10/2020	No
Institutional Ethics Committee Sri Ramachandra Institute of Higher Education and Research, Chennai	Approved	29/10/2020	No
Institutional Ethics Committee, BVDU, Pune	Approved	14/08/2020	No
Institutional Ethics Committee, Government Medical College, Nagpur	Approved	26/10/2020	No
Institutional Ethics Committee, JSS Medical College, Mysore	Approved	24/10/2020	No
Institutional Ethics Committee, PGIMER, Chandigarh	Approved	29/10/2020	No
Institutional Ethics Committee, T N Medical College & BYL Nair Hospital, Mumbai	Approved	27/10/2020	No
KEM Hospital Research Centre Ethics Committee, Pune	Approved	24/10/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	16/10/2020

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	**Years=**0

Trial	**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.