Clinical Trial Details (PDF Generation Date :- Wed, 29 Jun 2022 21:38:08 GMT)

CTRI Number	CTRI/2020/04/024749 [Registered on: 21/04/2020] - **Trial Registered Prospectively**
Last Modified On	27/07/2021
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects
Scientific Title of Study	A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects

Secondary IDs if Any

Secondary ID	Identifier
SII-rBCG/COVID-19/IN-01, version 5.0, dated 05.08.2020	Protocol Number

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

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Serum Institute of India Pvt. Ltd.

Primary Sponsor

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Name	Serum Institute of India Pvt Ltd
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Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
NIL	NIL

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?
Aditya Jyot Eye Hospital Ethics Committee, Mumbai	Approved	10/06/2020	No
Ethics Committee For Research On Human Subjects, MGM Aurangabad	Approved	07/05/2020	No
Ethics Committee of Pulse Multispeciality Hospital, Pune	Approved	29/04/2020	No
Ethics Committee, Jehangir Clinical Development Centre Pvt Ltd	Approved	27/04/2020	No
Ethics Committee, PGI Chandigarh	Approved	27/04/2020	No
Ethics Committee, Rao Nursing Home, Pune	Approved	28/04/2020	No
IEC, PCMCs, PGI, Yashwantrao Chavan Memorial Hospital	Approved	12/06/2020	No
Independent Ethics Committee of Symbiosis International University	Approved	12/05/2020	No
Institutional Clinical Ethics Committee , RGMC & CSMH, Thane	Approved	13/05/2020	No

Institutional Ethics Committe King Georges Medical University	Approved	06/05/2020	No
Institutional Ethics Committe, RCSMGMCIEC II, Kolhapur	Approved	29/04/2020	No
Institutional Ethics Committee National Institute of Cholera and Enteric Diseases	Approved	18/05/2020	No
Institutional Ethics Committee - Clinical Studies, Apollo Hospital, Chennai	Approved	29/05/2020	No
Institutional Ethics Committee Bharati Vidyapeeth Deemed University	Approved	29/04/2020	No
Institutional Ethics Committee for Human Research, Baroda Medical College, Vadodara	Approved	20/05/2020	No
Institutional Ethics Committee Max Super Speciality Hospital, Patparganj	Approved	05/05/2020	No
Institutional Ethics Committee Max Super Speciality Hospital, Saket	Approved	22/04/2020	No
Institutional Ethics Committee Mysore Medical College and Research Institute and Associated Hospitals	Approved	22/04/2020	No
Institutional Ethics Committee TNMC Nair Hospital	Approved	12/05/2020	No
Institutional Ethics Committee, AIIMS, Raipur	Approved	11/05/2020	No
Institutional Ethics Committee, B.J.G. Medical College and Sassoon General Hospitals, Pune	Approved	06/06/2020	No
Institutional Ethics Committee, D Y Patil Medical College, Navi Mumbai	Approved	01/06/2020	No
Institutional Ethics Committee, Fortis Hospital, Mumbai	Approved	09/06/2020	No
Institutional Ethics Committee,	Approved	04/05/2020	No

Government Medical College, Nagpur			
Institutional Ethics Committee, Grant Medical College, Mumbai	Approved	12/05/2020	No
Institutional Ethics Committee, Indraprastha Apollo Hospitals, New Delhi	Approved	11/05/2020	No
Institutional Ethics Committee, Krishna Institute of Medical Sciences, Karad	Approved	04/05/2020	No
Institutional Ethics Committee, Poona Medical Research Foundation, Pune	Approved	12/05/2020	No
Institutional Ethics Committee, PT. B D Sharma Post Graduate Institute of Medical Sciences, Rohtak	Approved	23/04/2020	No
Institutional Ethics Committee, SRM College Chennai	Approved	16/06/2020	No
Institutional Ethics Committee, SRMC Chennai	Approved	11/05/2020	No
KEM Hospital Research Centre Ethics Committee, Pune	Approved	20/04/2020	No
Nikop Institutional Ethics Committe	Approved	30/04/2020	No
Noble Hospital Institutional Ethics Committee	Approved	07/05/2020	No
Prakash Medical College, Institutional Ethics Committee	Approved	21/04/2020	No
Sahyadri Hospitals Ltd Ethics Committee	Approved	04/06/2020	No
Scientific Research and Ethics Review Committee, Batra Hospital and Medical Research Center, New Delhi	Approved	11/05/2020	No
Sir Ganga Ram Hospital Ethics Commitee	Approved	13/06/2020	No
Sri Venkateshwara Hospitals Ethics Committee	Approved	23/04/2020	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	31/08/2020

Health Condition / Problems Studied

Health Type	Condition
Patients	Coronavirus as the cause of diseases classified elsewhere
Patients	Encounter for immunization

Intervention / Comparator Agent

Type	Name	Details
Intervention	recombinant BCG vaccine, VPM1002	Dose : 0.1 ml, single dose of the reconstituted vaccine to be administered as an intradermal injection
Comparator Agent	Placebo, 0.9% sodium chloride	Dose : 0.1 ml, single dose to be administered as an intradermal injection

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	99.00 Year(s)
Gender	Both
Details	1. Male or Female subjects ? 18 years of age at high-risk of SARS-CoV-2/COVID-19 infection 2. Test negative for SARS-CoV-2 infection (RT-PCR test) at screening 3. Capable of giving informed consent

Exclusion Criteria

Exclusion Criteria	
Details	1. Previous history of Tuberculosis or known active Mycobacterium tuberculosis infection 2. Received BCG vaccine within one year prior to screening 3. Fever (greater than or equal to 38 ºC/100.4°F) or any other respiratory symptoms/illnesses within the past 14 days 4. Pregnant or lactating women 5. Women of child-bearing potential not agreeing to use adequate contraception 6. Current active viral or bacterial infection 7. Expected vaccination during the study period, independently of the type of vaccination 8. Severely immunocompromised subjects. 9. Active solid or non-solid malignancy or lymphoma within the prior two years 10. Individuals known to be hypersensitive to any component of the vaccine 11. Eczema or other significant skin lesion or infection at the site/s of injection. 12. Any other medical condition which in the opinion of the investigator may affect the subject’s safety or study participation and conduct

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.Number of subjects with laboratory confirmed COVID-19 infection among HCWs 2.Number of subjects with laboratory confirmed COVID-19 infection among other high-risk subjects 3.Number of laboratory confirmed COVID-19	up to 6 months (180 days) following vaccine administration

infection with severe, critical or life-threatening disease as assessed by Investigator among HCWs 4.Number of laboratory confirmed COVID-19 infection with severe, critical or life-threatening disease as assessed by Investigator among other high-risk subjects	

Secondary Outcome

Outcome	Timepoints
1.Duration of COVID-19 symptoms in HCWs 2.Duration of COVID-19 symptoms in other high-risk subjects 3.Severe Disease Outcomes in HCWs 4.Severe Disease Outcomes in other high-risk subjects 5.Severe Disease Outcomes among in elderly subjects (greater than or equal to 60 years) 6.Severe Disease Outcomes among subjects with Co-morbidities 7.Incidence of Adverse Events and Serious Adverse Events	up to 6 months (180 days) following vaccine administration

Target Sample Size	**Total Sample Size=**5946 **Sample Size from India=**5946 **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)	21/04/2020
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	
Brief Summary	This is a placebo controlled, multicentric, randomized, double blind, adaptive study to evaluate the reduction in infection incidence and severity of SARS-CoV-2/ COVID-19 infection among high-risk subjects by enhanced trained immune response through VPM1002 vaccine. Subjects who provide informed consent will be assessed for eligibility criteria. The subjects who fulfill all the eligibility criteria will be randomized in a 2:1 ratio to receive a single dose (0.1 ml) of either VPM1002 or placebo, administered as an intradermal injection. The duration of follow-up will be based on the results of interim analysis however the maximum follow-up period will be up to 180 days.