Clinical Trial Details (PDF Generation Date :- Sat, 30 Sep 2023 10:48:28 GMT)

CTRI Number	CTRI/2017/03/008266 [Registered on: 30/03/2017] - **Trial Registered Prospectively**
Last Modified On	26/09/2023
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	A study to check the efficacy and safety of recombinant BCG vaccine in prevention of TB recurrence.
Scientific Title of Study	A Multicenter Phase II/III Double – Blind, Randomized, Placebo Controlled study To evaluate the Efficacy and the safety of VPM1002 in the prevention of tuberculosis (TB) recurrence In pulmonary TB patients after successful TB treatment.

Secondary IDs if Any

Secondary ID	Identifier
VPM1002-IN-3.01TBR VERSION:3.0DATED 23 MARCH 2019	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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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 Pvt. Ltd. 212 / 2, Off Soli Poonawalla Road, Hadapsar, Pune – 411028, India

Primary Sponsor

Primary Sponsor Details	
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
Bangladesh
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Ethics Committee S P Medical College Bikaner	Approved	29/05/2021	No
Ethics Committee, B J Medical College and Sasoon General Hospital Pune	Approved	29/03/2017	No
Institute Ethics Committee (Human Studies) Jawaharlal Institute of Postgraduate Medical Education and Research	Approved	16/02/2018	No
Institutional Ethics Committee Christian Medical College, Ludhiana	Approved	26/10/2017	No
Institutional Ethics Committee for Research on human Subjects, Sewagram	Approved	18/08/2017	No
Institutional Ethics Committee King George Hospital Visakhapatanam	Approved	15/07/2021	No
Institutional Ethics Committee L R S Institute of Tuberculosis	Submittted/Under Review	No Date Specified	No

and Respiratory Diseases			
Institutional Ethics Committee of Bhagwan Mahavir Medical Research Center for Bio-Medical Research Hydrabad	Approved	24/07/2017	No
Institutional Ethics Committee PGIMER	Approved	01/02/2018	No
Institutional Ethics Committee, GMC, Nagpur	Approved	10/06/2022	No
Institutional Review Board, Christian Medical College, Vellore	Approved	10/04/2017	No
KEM Hospital Research Center Ethics Committee	Approved	24/06/2017	No
Manipal University Ethics Committee, Manipal	Approved	20/03/2017	No
National Institute for Research in Tuberculosis Institutional Ethics Committee	Approved	28/02/2018	No
Prof M Vishwanathan Diabetes Research Center Institutional Ethics Committee	Approved	14/03/2017	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	31/05/2022

Health Condition / Problems Studied

Health Type	Condition
Patients	Pulmonary TB Patients after successfull TB treatment and were declared cured

Intervention / Comparator Agent

Type	Name	Details
Intervention	VPM1002	The active ingredient of the recombinant BCG vaccine, VPM1002 is Mycobacterium bovis rBCG?ureC::Hly+, freeze-dried and standardized to number of viable mycobacteria (colony forming units; CFU) per application
Comparator Agent	Placebo	Freeze dried powder containing dextran, glucose and water for injection as solvent

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	65.00 Year(s)
Gender	Both
Details	1. Males or females aged more than or equal to 18 and less than or

	equal to 65 years 2. Bacteriologically confirmed Category I pulmonary TB patients (including controlled diabetics with HbA1c level less than or equal to 7% and non-diabetics) who successfully completed ATT as per national guidelines. 3. Must have a sputum sample showing bacteriologic confirmation of cure - defined as smear negative. 4.Female participants who are currently using reliable methods of birth control, have a negative pregnancy test during screening and have no intention to become pregnant for at least 3 months post-vaccination

Exclusion Criteria

Exclusion Criteria	
Details	1. Reactive serology for HIV 2. History of extrapulmonary TB 3. Current or known history or family history of multidrug-resistant or extensively-drug-resistant TB 4. Known or suspected impairment of immunological function 5. Pregnant and / or lactating female participants.

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

Primary Outcome

Outcome	Timepoints
Bacteriologically confirmed TB recurrence cases	From two months to 12 months after vaccination

Secondary Outcome

Outcome	Timepoints
Efficacy: Overall TB recurrence (Bacteriologically confirmed and clinically diagnosed cases) Safety: o Solicited local and regional reactogenicity events within 2 months following study vaccination o Unsolicited adverse events o SAEs throughout the study period	From two months to twelve months after vaccination

Target Sample Size	**Total Sample Size=**2000 **Sample Size from India=**2000 **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)	01/07/2017
Date of First Enrollment (Global)	01/07/2017
Estimated Duration of Trial	**Years=**1 **Months=**2 **Days=**0
Recruitment Status of Trial (Global)	Closed to Recruitment of Participants
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	NA
Brief Summary	This is Phase II/III study designed as a multicenter, double-blinded, randomized, placebo-controlled trial with two groups of adults successfully cured of TB receiving either VPM1002 or placebo. Single dose of VPM1002 / placebo will be administered to former TB patients who have successfully completed Category I ATT, were declared cured. The vaccine will be administered intradermally.