



INDIAN COUNCIL OF MEDICAL RESEARCH

Department of Health Research – Ministry of Health & Family Welfare
Government of India

Press Release

ICMR launches Vaccine trial to prevent occurrence of TB among close contacts of a TB patient

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The Indian Council of Medical research today launched a vaccine trial to prevent occurrence of TB among close contacts of a TB case (patient). This vaccine trial is an important step in prevention and decreasing the burden of this disease.

Since, India has the highest number of TB cases in the world; ICMR is undertaking this 1st TB vaccine clinical trial after the famous BCG vaccine trial undertaken decades back. After a detailed landscape analysis of the available lead vaccine candidates, two potential vaccine candidates VPM 1002 and MIP were shortlisted for taking forward through the phase III vaccine trial in healthy house hold contacts of sputum smear positive TB patient.

The two vaccines include VPM1002, which is produced by Serum Institute of India, Pune and the other vaccine is MIP (Mycrobacterium Indicus Pranii).

This clinical trial will evaluate the safety and efficacy of these two vaccines in a single trial against control group with no vaccine. The study would enroll 12000 healthy Household contacts of sputum smear positive TB cases that are at high risk of contracting the disease, from 7 sites in 6 states (Delhi, Karnataka, Maharashtra, Orissa, Tamil Nadu and Telangana) of the country.

At the launch of the clinical Trial for the vaccine at NITRD, Delhi, Dr. Balram Bhargava, Secretary, Department of Health Research and Director General, ICMR expressed the appreciation for the government's support and researchers involved in the trial. He said that the clinical trials are needed in

India to show that the vaccine is safe and effective, and that it can provide protection to Indian populations where the disease is endemic.

The ultimate goal is to develop a vaccine that can prevent active TB and be a part of large campaigns aimed at eliminating the disease. This clinical study in India could help achieve this goal and significantly advance the global fight against Tuberculosis, he added.

Dr. Rohit Sarin, Director, NITRD said that this is the much awaited trial and assured full support in timely completion of the trial.

The study has approval of all statutory regulatory bodies of India as per the Indian regulatory guidelines. The study has been started at the first site at NITRD, New Delhi today and would be subsequently initiated at other sites; the goal is to complete its enrollment within 7 to 8 months.

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