

# BCG REVACCINATION STUDY IN HIGH-RISK ADULTS TO BEGIN IN 23 STATES

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December 02, 2023 09:00 pm | Updated 09:00 pm IST

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Twenty-three States have consented to participate in the BCG revaccination study in adults that will be undertaken in a “programme implementation study mode” to evaluate the effectiveness of the vaccine in reducing TB disease incidence. The study will target some high-risk groups — those older than 50 years, prior TB disease, underweight adults, diabetics, and those who smoke and consume alcohol. The phase-1 of the study will be conducted in Uttar Pradesh and Madhya Pradesh, says a Delhi-based official.

No clinical trials have been carried out in India to study the efficacy of BCG revaccination in adults to prevent TB disease, and studies in other countries have thrown up mixed results. Two clinical investigation studies (2019 and 2023) by St. John’s Research Institute, Bengaluru have found BCG revaccination in adults to be significantly immunogenic.

Despite the recommendation of an expert committee that a clinical trial be carried out first, the government has decided to go ahead with the programme implementation study. “An expert committee constituted by ICMR recommended that a robust trial be carried out in India and implementation at population-level be undertaken once evidence of efficacy was available,” says Dr. Soumya Swaminathan, former Chief Scientist at WHO and a member of the expert committee. “Most studies of BCG revaccination globally have not found major impacts on reducing TB incidence. Therefore, it is not recommended by the WHO currently. However, a recent phase-2 trial in South Africa suggested it may prevent TB infection. Hence, further trials are warranted to assess the effectiveness of BCG revaccination in different populations, age groups, by timing of revaccination and types of TB.”

Since the government felt that a trial would take too long to complete and wanted to implement BCG revaccination at scale, the committee had suggested that some districts be used as an intervention arm and some as the control arm, and TB incidence be captured over a couple of years. Accordingly, 50% of the districts in a State will be included in the intervention arm and the remaining 50% will act as control.

“WHO does not currently recommend programmatic or pilot BCG revaccination [even in high-burden countries such as India],” Dr. Birgitte Giersing, Team Lead - vaccine platforms & prioritization, WHO, says in an email to *The Hindu*. The 2018 BCG vaccine position paper by WHO does not advocate BCG revaccination in adults. It says: “Studies have shown minimal or no evidence of any additional benefit of repeat BCG vaccination against TB or leprosy.

Therefore, revaccination is not recommended.”

The protective effect of a single dose of the vaccine given to infants in India wanes within a short time. A 15-year follow-up study found that at the end of 7.5 years there was “complete lack of protective efficacy” in children. Even if revaccination offers protection in adults, the duration of protection remains to be seen.

Incidentally, while NIRT in Chennai will be conducting a BCG booster dose clinical trial in children aged 6-18 years, the BCG revaccination study in adults is being undertaken mainly based on the retrospective data analysis of a small sub-group of the Chingleput BCG vaccination trial conducted in 1968. In the 1968 trial, 2,890 adults received a BCG revaccination and 1,546 did not, and the efficacy of the vaccine to reduce TB incidence was found to be 36%. But the protective efficacy was seen only at the end of 15 years of follow-up, and the protective effect of BCG revaccination was significant only in the 31-40 years age group.

The Chingleput BCG revaccination study has several limitations — the sample size is small, potential confounders such as nutritional status, diabetes, smoking and alcohol consumption, and TB exposure status are not known, and the time interval between the first dose and BCG revaccination is also not known.

“We could carry out a ‘phase 3’-like randomised controlled trial, or we could carry out a ‘phase 4’-like (‘pilot’) pragmatic evaluation of the roll-out of the vaccine. As BCG is an already-licensed vaccine... the effectiveness information India (and the world) needs on whether BCG revaccination prevents TB disease could be gained from a phase 4-like (‘pilot’) study as long as it is done well enough,” Dr. Richard White, Professor of infectious disease modelling at the London School of Hygiene & Tropical Medicine says in an email.

Tamil Nadu, which has consented to participate in the study, has 44 TB districts. Half of these will be earmarked as intervention arm and the remaining as control. “Since adults belonging to high-risk groups are to be studied, the number of consenting participants will run into lakhs,” says Dr. T.S. Selvavinayagam, Director of Public Health and Preventive Medicine, Chennai. “The safety profile of BCG revaccination will be studied programmatically, while a sub-group of participants running to a few thousands will be followed-up for two-three years by NIRT for vaccine efficacy.” The study will begin in Tamil Nadu once the State government approves it.

Kerala, Bihar, Chhattisgarh, West Bengal and Uttarakhand that have not consented to participate in the study. “The field constraints to carry out the study is the only reason why Kerala did not consent to participate,” a Kerala official says. “The staff involved in the universal immunisation programme will be overburdened when BCG revaccination is included. There are gaps in the immunisation programme in Kerala after the pandemic. The focus is on closing this gap. So Kerala did not want to begin the BCG revaccination programme now.”

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