

Successful TB vaccine moves forward after phase 2 trial

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DAR-901 study team in Tanzania. Credit: The Geisel School of Medicine at Dartmouth

Results from the Phase 2 trial of the DAR-901 tuberculosis (TB) vaccine were announced today by investigators at Dartmouth's Geisel School of Medicine and published in the journal *Vaccine*. The three-year trial was conducted among 650 adolescents in Tanzania, a nation with high rates of TB infection, and showed that the vaccine was safe and induced immune responses against the disease.

Tuberculosis is most common infectious disease cause of death in the world (1.5 million deaths per year compared to 1 million to date from COVID-19) and a new preventive vaccine is a major global health priority. Ford von Reyn, MD, professor of medicine at the Geisel School of Medicine and lead for the vaccine development program, explained that the trial moves the Dartmouth TB vaccine one step closer to a full Phase 3 efficacy trial against TB disease. "Our collaborators in Tanzania deserve credit for their excellent work in conducting a clinical trial to rigorous international standards and moving DAR-901 forward to Phase 3," said Von Reyn.

The vaccine trial was a collaboration between Geisel, the Muhimbili University of Health and Allied Sciences (MUHAS) in Tanzania, the Tokyo Medical and Dental University in Japan, Tufts

University School of Medicine, and the Boston University School of Public Health.

Tanzanian students age 13-15 with no evidence of prior TB infection were recruited from schools in Dar es Salaam to receive three injections of the DAR-901 vaccine or placebo in the double-blind trial. All participants had already received the current TB vaccine (BCG) at birth and DAR-901 was administered as a booster. After immunization all participants were followed for safety and re-tested for TB infection annually for three years.

Senior Tanzanian collaborator Kisali Pallangyo, MD, MMed, professor of internal medicine at MUHAS said, "The three dose schedule of DAR-901 was very well tolerated by the students with minimal local reactions and no serious side effects, a very positive result".

The study was conducted as a Prevention of Infection (POI) trial, a new design for TB vaccine [trials](#). TB infection is the first phase of the human response to TB exposure. Because TB infection is not associated with symptoms it can only be detected by a skin test or an IGRA blood test. Development of TB infection is favorable in most people because it provides immunity against progression to TB disease. Among 100 people who acquire TB infection, 90-95% never develop TB disease; only 5-10% will progress to actual TB disease over a lifetime. Although it has been reasoned that if a vaccine can prevent TB infection it will also prevent TB disease, the Dartmouth trial raises questions about this assumption.

DAR-901 was manufactured from SRL172, an inactivated whole cell [vaccine](#) which had already been shown to reduce the risk of TB disease in a 2,000 subject Phase 3 trial among subjects with HIV. In the new Phase 2 trial DAR-901 did not reduce the risk of new TB infection, a finding that was not anticipated. Participants who received DAR-901 and did develop new TB infection had

greater immune responses to TB than participants who received placebo. The investigators believe this finding suggests DAR-901 may prevent TB disease by inducing the favorable [immune response](#) that protects 90-95% of persons with TB [infection](#) from ever developing TB [disease](#). This hypothesis will be tested in a large Phase 3 Prevention of Disease (POD) trial that would be required for licensure.

More information: Patricia Munseri et al, DAR-901 vaccine for the prevention of infection with Mycobacterium tuberculosis among BCG-immunized adolescents in Tanzania: A randomized controlled, double-blind phase 2b trial, *Vaccine* (2020). [DOI: 10.1016/j.vaccine.2020.09.055](https://doi.org/10.1016/j.vaccine.2020.09.055)

Provided by The Geisel School of Medicine at Dartmouth

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