

Clinical trials underway for adult TB vaccine

An ongoing clinical trial is underway to further evaluate a new tuberculosis (TB) vaccine candidate MTBVAC in an adult endemic population.



MTBVAC is a live, attenuated form of Mycobacterium tuberculosis, the bacterium that causes TB in humans. It therefore might be more effective in preventing TB disease than BCG, the only vaccine currently used to prevent TB, which is derived from a bovine, rather than human, strain of the bacteria.

BCG is effective in preventing severe TB disease in infants and children, but only has a variable effectiveness in disease prevention in adults.

A Phase Ia trial showed that MTBVAC demonstrated a similar safety profile to BCG at a similar dose.

The trial is a collaboration between the University of Zaragoza (Spain), which developed the vaccine candidate; the Spanish biopharmaceutical company Biofabri, which is the vaccine candidate sponsor; the South African Tuberculosis Vaccine Initiative (Satvi); and the TuBerculosis Vaccine Initiative (TBVI). The International Aids Vaccine Initiative (Iavi) is the trial sponsor. Funding is provided by the US National Institutes of Health (NIH) and the US Department of Defense through its Congressionally Directed Medical Research Programme.

A-050 trial

Designated A-050, the trial is a Phase Ib/IIa safety and dose-finding study of MTBVAC. This trial is designed to test different doses of MTBVAC and collect additional safety and immunogenicity information in healthy adults with and without evidence of having been previously infected with TB bacteria. It also has the potential to show whether vaccination with MTBVAC produces an immune response distinct from the response to BCG. In A-050, up to 144 participants at Satvi trial site in Worcester, South Africa, will receive either one administration of MTBVAC at different doses or BCG at the standard adult dose. Participants will be monitored for safety and immune response for 12 months after vaccination.

TB is one of the top 10 leading causes of all deaths worldwide and kills about 1.6-million people annually. Each year, about 10-million new cases of TB are detected. The scale of the problem is so great that one in four people globally are infected with the bacteria that cause TB. The World Health Organisation estimates that the annual global economic burden of the TB epidemic is more than \$20bn (over R296bn). Experts widely agree that new, more effective TB vaccines will be necessary to address the global TB crisis.

Results for A-050 are expected in 2020.

Source: University of Cape Town

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