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Effort to develop vaccine to prevent progression from latent to active TB disease

Study finds vaccine well tolerated, induces specific immune response

A global effort is underway to develop a new TB vaccine that blocks progression from the precursor phase of TB, so-called latent infection, to active disease. A vaccine that is effective in infected adults will be key to interrupting the cycle of transmission and halting the global epidemic.

Researchers at the South African Tuberculosis Vaccine Initiative (SATVI) at the University of Cape Town (UCT), the Infectious Disease Research Institute (IDRI) and Aeras (a non-profit, global biotech organisation developing new TB vaccines) have released the first results from a clinical trial reporting safety and induced immune responses of ID93 + GLA-SE, a novel tuberculosis vaccine candidate developed by scientists at IDRI. The trial in South African adults demonstrated that the vaccine was well tolerated, had an acceptable safety profile and induced a specific immune response, supporting further development and clinical testing of this novel vaccine candidate.

The safety and comprehensive immune responses results of the ID93 + GLA-SE vaccine were published in a special edition of The Lancet Respiratory Medicine. The researchers tested escalating doses of the vaccine in 54 healthy adults living outside of Cape Town. At the time of vaccination, some of the study participants had been living with a natural infection of *Mycobacterium tuberculosis (M.tb)*, the bacterium that causes TB disease.

Professor Mark Hatherill, the lead researcher from UCT, said “globally, approximately 10% of people infected with the TB bug develop TB disease over their lifetime, but a vaccine such as ID93 + GLA-SE could help to prevent the disease, which is spread by coughing. In South Africa, 50-80% of adults are infected with *M.tb*, and the incidence of TB disease is one of the highest in the world, so there is an urgent need to stop TB before it is spread.”

Four proteins from *M.tb* are included in the ID93 + GLA-SE vaccine, none of which have ever been tested in a vaccine formulation in humans before. The scientists combined the vaccine proteins with a special adjuvant compound, an oil emulsion called GLA-SE, that greatly enhances immune responses to vaccination. This is the first report of this particular adjuvant – developed by IDRI – in a clinical trial for a TB vaccine. The vaccine was given to participants by injection into the arm muscle, and was well tolerated, demonstrating an acceptable safety profile in adults living in a setting where TB is endemic.

The ID93 + GLA-SE vaccine induced potent immune responses, in the form of both antibodies and T cells.

Dr Adam Penn-Nicholson, immunologist at SATVI and lead author of the published paper, said: “We found that the vaccine induces immune responses with distinct characteristics to each of the TB antigens included in the ID93 + GLA-SE vaccine. We believe that a response with diverse

characteristics may be more likely to provide immunity than a narrow response against the TB bacterium."

The ID93 + GLA-SE vaccine is now advancing to the important next phase of human studies. A trial is underway in which the vaccine has been given to patients who have finished TB treatment to test whether it is safe and induces immune responses that might prevent another episode of TB disease. The scientists are currently analysing results from this trial and the findings are likely to be available later this year.

Tuberculosis causes 1.7 million deaths a year and is the biggest global cause of mortality from any infectious disease. The World Health Organization reports that despite accounting for about 2% of deaths globally, TB receives only 0.25% of the estimated US$265 billion spent worldwide on medical research each year. Dr Rhea Coler, IDRI's Senior Vice-President of Preclinical and Translational Research, said: "TB research is significantly underfunded. Governments must make a greater commitment to fund the R&D [research and development] that will end TB once and for all".

To access the full study click here

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