

Results from new trial of the candidate TB vaccine MTBVAC offer hope for control of tuberculosis in infants

First trial of a new live attenuated *Mycobacterium tuberculosis* vaccine in infants

Results published in *The Lancet Respiratory Medicine* on 12 August

Cape Town/Porriño/Zaragoza/Lelystad: The South African Tuberculosis Vaccine Initiative (SATVI), Biofabri, the University of Zaragoza and TuBerculosis Vaccine Initiative (TBVI) announced promising new safety and immunogenicity results for the live, attenuated *Mycobacterium tuberculosis* vaccine MTBVAC in BCG-naïve South African infants, appearing online in [The Lancet Respiratory Medicine](#) on 12 Aug 2019.

This Phase 1b study, conducted in a TB endemic community, showed that vaccination of infants with MTBVAC displayed a similar safety profile and had indistinguishable reactions at the injection site to that of the current licensed TB vaccine, Bacille Calmette-Guérin (BCG), which has an excellent safety record.

Vaccination with MTBVAC induced a long-lasting immune response of greater magnitude than that of BCG at a comparable dose. These promising data support further progression of MTBVAC through ongoing Phase 2a dose-defining studies and into large-scale infant efficacy trials.

MTBVAC was also shown to induce dose-dependent conversion and in some cases reversion of the QuantiFERON test (QFT), a diagnostic tool originally designed to detect infection with *M. tuberculosis*. This is not surprising since MTBVAC is a live, attenuated *M. tuberculosis* vaccine. In fact, these outcomes may be seen as an encouraging sign of stimulating immune responses against *M. tuberculosis*, but represent a challenge to interpretation of QFT results in MTBVAC recipients. Ongoing Phase 2a and future efficacy studies in TB endemic countries will allow more extensive evaluation of QFT dynamics in infants, and encourage development of new diagnostic tests to differentiate the MTBVAC-induced response from natural *M. tuberculosis* infection.

Positive assessment of results

Professor Mark Hatherill, SATVI Director: “These exciting results are an important step towards a more effective TB vaccine, and support plans for a much larger trial to better define the safety and efficacy of MTBVAC in infants living in TB endemic countries.”

Professor Tom Scriba, SATVI Deputy Director, Immunology: “The encouraging results from this trial show that MTBVAC is capable of inducing robust and durable immune responses and trigger the next stage of evaluation for this vaccine candidate. “

Esteban Rodríguez General Manager of Biofabri: In 2008, Biofabri acquired the commitment to make available MTBVAC vaccine worldwide and at an affordable price. Such a commitment enhances Biofabri's involvement in the fight against tuberculosis disease, particularly in low income countries.

Carlos Martin of University of Zaragoza: The next step is to demonstrate the efficacy of MTBVAC in tuberculosis endemic countries. The sooner we can show the efficacy of MTBVAC in clinical trials, the earlier MTBVAC could help us save millions of lives.

Jelle Thole of TBVI: A new vaccine against tuberculosis is urgently needed for all age groups. It is therefore very encouraging to see these promising results for a new vaccine that offers hope for a better vaccine that can be delivered to infants.

About MTBVAC

MTBVAC is the first live-attenuated *Mycobacterium tuberculosis* candidate vaccine in clinical trials. MTBVAC was generated by genetically attenuating a pathogenic *M. tuberculosis* strain isolated from a TB patient. It is hypothesised that MTBVAC is a more effective vaccine than the currently used BCG vaccine, as it is more similar to the human pathogen and carries a much broader repertoire of TB antigens. MTBVAC has been tested in Swiss and South African adults and in South African infants. We aim to develop MTBVAC as a priming vaccine for newborn infants, and as a booster vaccine for adolescents and adults.

About the partners

About Biofabri

BIOFABRI is a biopharmaceutical company that was created in 2008 with the vision to research, develop and manufacture human vaccines. BIOFABRI is focused on human health, with strong technical, development and manufacturing capabilities and a proven track record. Biofabri belongs to Zandal a Spanish biopharmaceutical business group which specializes in development, manufacture and marketing of biotechnology and pharmacy products for both humans and animals. Biofabri is also the manufacturer of MTBVAC.

www.biofabri.es

About the University of Zaragoza

The University of Zaragoza is the main centre of technological innovation in the Ebro Valley and has great prestige among Spanish and European universities. The University of Zaragoza participates in various exchange programmes, collaborating with universities and research centres from Europe, Latin America and the USA, thereby strengthening its international standing. Microbiologists of our university belonging to the CIBERES led the research and discovery of the live vaccine candidate MTBVAC. Within the TBVI consortium, the discovery phase of MTBVAC has included rigorous preclinical characterization by independent laboratories and research groups. Biofabri is the industrial partner of the University of Zaragoza, responsible for the Industrial and Clinical Development of MTBVAC.

<http://www.unizar.es>

About TBVI

The TuBerculosis Vaccine Initiative (TBVI) is a non-profit foundation that facilitates the discovery and development of new, safe and effective TB vaccines that are accessible and affordable for all people. TBVI integrates, translates and prioritises R&D efforts to discover and develop new TB vaccines and biomarkers for global use. TBVI provides essential services that support the R&D efforts of its 50 consortium partners from academia, research institutes and private industry in the TB vaccine field. These services include project identification, design and development; project management; resource mobilisation; knowledge development, exchange and networking; and technical advice and support for product and clinical development.

www.tbvi.eu

About SATVI

The South African Tuberculosis Vaccine Initiative (SATVI) is a TB research group based at the Faculty of Health Sciences of the University of Cape Town. SATVI is regarded as a worldwide leader in TB vaccine research and has conducted 28 Phase I–IV trials of 9 different TB vaccine candidates since 2005. SATVI's research focus is understanding the risk for, and protection against, *M. tuberculosis* infection and disease, in order to develop more effective vaccines and preventive strategies for global impact on the TB epidemic.

www.satvi.uct.ac.za

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