Researchers test a new TB vaccine

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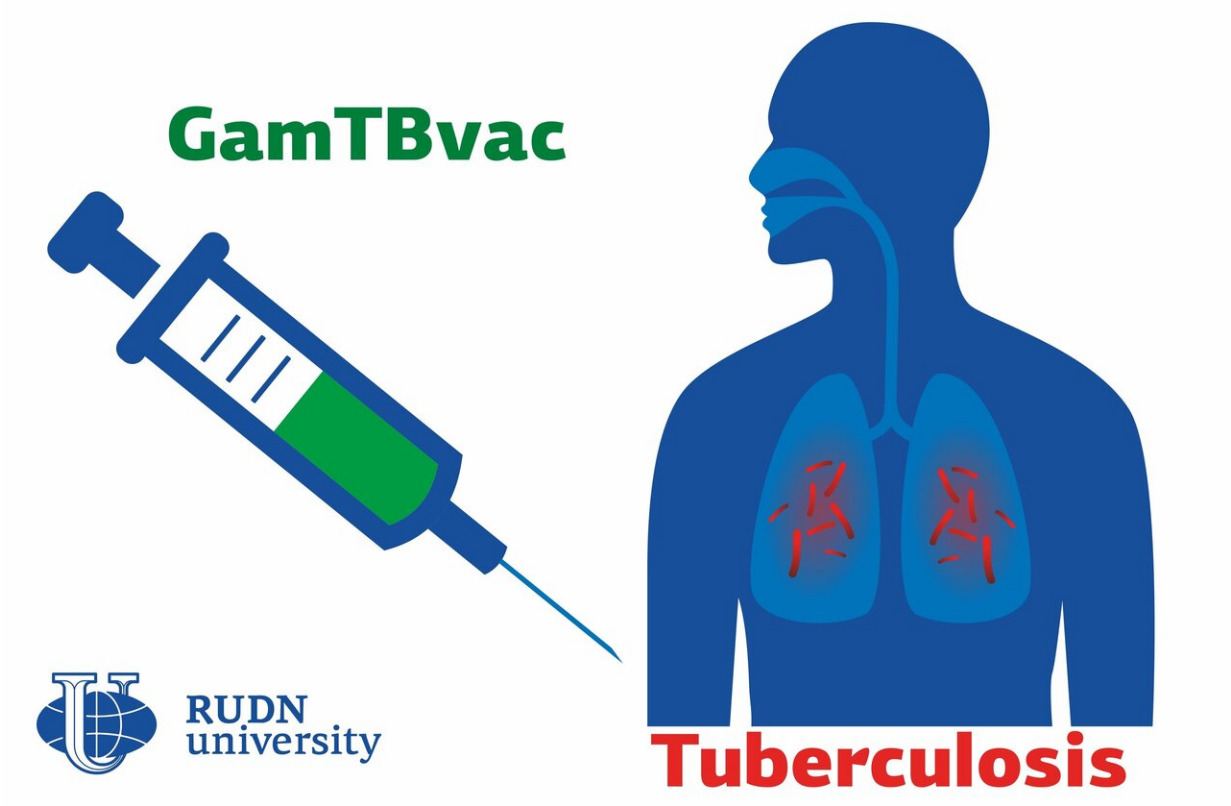

Credit: RUDN University

A clinical pharmacologist from RUDN University together with his colleagues from Gamaleya Research Institute of Epidemiology and Microbiology completed the second stage of a clinical trial of a new TB vaccine that was conducted with the participation of 180 volunteers. The trial confirmed the safety and efficiency of the vaccine. The results of

the study were published in the *Vaccines* journal.

Every year, Mycobacterium tuberculosis infects 10 mln and kills 1.4 mln people which makes prevention and treatment of tuberculosis one of the priority goals of the World Health Organization. Currently, the main weapon against tuberculosis is the BCG vaccine that prevents tuberculous meningitis and miliary tuberculosis. However, it is still unable to protect us from all forms of the disease. Moreover, for unknown reasons, it can be less effective in some populations than in others. A medic from RUDN University together with his colleagues conducted a clinical trial of a new TB vaccine that is supposed to enhance the immunity acquired after BCG vaccination.

"GamTBvac is a TB vaccine that contains three antigene fragments of Mycobacterium tuberculosis. It is these elements that our immune system is expected to react to in order to develop immunity. For better stability, the fragments are bound with a dextran-binding domain–a fragment of proteins taken from the bacterium Leuconostoc mesenteroides. The vaccine also contains an adjuvant, that is, an additional substance that enhances the immune response. The adjuvant contains dextran, diethylaminoethyl dextran, and oligodeoxynucleotides," said Prof. Sergey Fitilev, MD, from the Department of General and Clinical Pharmacology, RUDN University.

Currently, 14 alternative vaccines that could be used on their own or in combination with BCG are being developed all over the world. They include mild strains of the human and bovine tubercle bacillus, DNA vaccines, and recombinant subunit vaccines (the type that GamTBvac belongs to). An earlier study with 60 volunteer participants had already demonstrated the safety of GamTBvac and confirmed that a half dosage causes a stable and active immune response without considerably affecting the well-being of the patients. The second stage was a double-blind, randomized, placebo-controlled trial that included 180 participants

(all vaccinated with BCG).

Each participant received two 0.5 ml intradermal injections of either the vaccine or placebo, one eight weeks after the other. Because of the double-blind nature of the study, neither the doctors nor the patients knew who received the vaccine and who was injected with placebo until the end of the trial. This helped the team avoid any subjective interpretation of the results. Between the 14th and the 150th day after the vaccination, the team took blood samples from the patients eight times to study their immune reactions. The level of gamma interferons (immune proteins) was the highest on the 21st day, and on the 150th day, it exceeded the pre-vaccination levels two times. 94% to 98% of the participants developed an immune response to the fragments of Mycobacterium tuberculosis. Although it is still too early to confirm that this is enough to protect one from TB, these results are important for future studies.

More information: Artem P. Tkachuk et al. Safety and Immunogenicity of the GamTBvac, the Recombinant Subunit Tuberculosis Vaccine Candidate: A Phase II, Multi-Center, Double-Blind, Randomized, Placebo-Controlled Study, *Vaccines* (2020). DOI: 10.3390/vaccines8040652

Provided by RUDN University