

Multiple shots of the BCG vaccine protect type 1 diabetics from COVID-19

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Researchers at Massachusetts General Hospital (MGH), published a new paper in *Cell Reports Medicine* demonstrating the protective potential of multiple doses of the Bacillus Calmette-Guerin (BCG) vaccine against COVID-19 and other infectious diseases.

In a double-blind, placebo-controlled study of patients with type 1

diabetes conducted at the start of the pandemic (before COVID-specific vaccines were available), the researchers found that 12.5% of placebo-treated individuals and 1% of BCG-treated individuals met criteria for confirmed COVID-19, yielding a [vaccine effectiveness](#) of 92%.

The BCG-vaccinated group also displayed protective effects against other infectious diseases, including fewer symptoms, lesser severity and fewer infectious disease events per patient. No BCG-related systemic adverse events occurred.

BCG's broad-based infection protection suggests that, in addition to COVID-19, may potentially provide protection against new SARS-CoV-2 variants and other pathogens.

The researchers are hoping the results will spur a larger scale study of the effects of the BCG vaccine in patients with type 1 diabetes, considered among the most vulnerable groups to COVID-19.

The BCG vaccine is an avirulent tuberculosis strain *Mycobacterium bovis* historically given to protect against tuberculosis and, since its introduction in 1921, has been the most widely administered vaccine in the history of medicine.

Considered to be extremely safe, BCG is on the World Health Organization's List of Essential Medicines and is given to roughly 100 million children per year globally. BCG is also one of the most affordable medicines, costing less than a dollar a dose in many parts of the world.

"Multiple studies have shown that adults with type 1 diabetes who are diagnosed with COVID-19 are at increased risk of severe illness.

"We found that three doses of BCG administered prior to the start of the

pandemic prevented infection and limited [severe symptoms](#) from COVID-19 and other infectious diseases.

"Unlike the antigen-specific vaccines currently in use to prevent COVID-19, BCG's mechanism of action is not limited to a specific virus or infection," says Denise Faustman, MD, Ph.D., director of the Immunobiology Laboratory at Massachusetts General Hospital.

The participants in the COVID trial had previously enrolled in a clinical trial testing the effectiveness of the BCG [vaccine](#) for type 1 diabetes. Participants in the test group had received multiple vaccinations prior to the onset of the pandemic in early 2020.

"This data set is unique and exciting because the patients were all vaccinated with multiple doses of BCG prior to the onset of the epidemic. Prior to the trial they had no known exposure to tuberculosis or prior BCG vaccination. This eliminates the major confounding factors that have limited other trials.

"The results support the idea that BCG needs time to have a clinical effect, but its effects may then be very lasting and durable," says Hazel Dockrell, London School of Hygiene & Tropical Medicine, an [infectious diseases](#) expert who was not officially involved in the study.

The 144 adult type diabetics (96 BGC treated and 48 placebo) analyzed in the COVID-19 trial were part of an ongoing Phase IIb clinical trial testing BCG as a treatment for adults with established type 1 diabetes. Patients were followed for COVID-19 related outcomes for 15 months.

Outcomes for the COVID-19 trial included: COVID-19 infection rate, COVID-19 related symptoms, reduction overall infections disease and SARS-CoV-2 antibody-level presence and intensity. The type 1 diabetes outcomes were not unblinded as part of this study and will be unblinded

at the completion of the trial in 2023.

More information: Denise L. Faustman et al, Multiple BCG vaccinations for prevention of COVID-19 and other infectious diseases in Type 1 diabetes, *Cell Reports Medicine* (2022). [DOI: 10.1016/j.xcrm.2022.100728](https://doi.org/10.1016/j.xcrm.2022.100728)

Provided by Massachusetts General Hospital

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