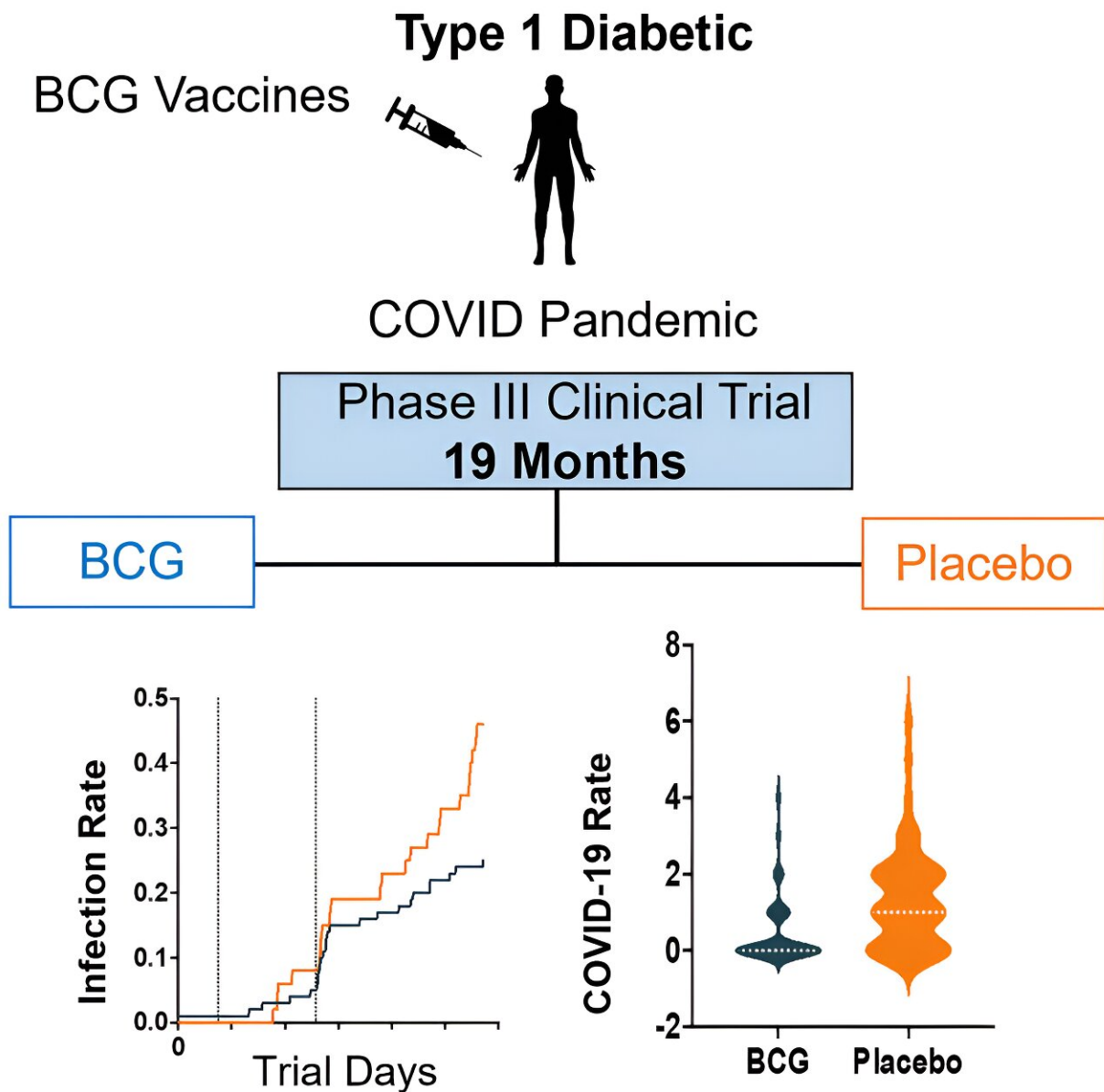


Century-old vaccine found to protect type 1 diabetics from infectious diseases

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Graphical abstract. Credit: *iScience* (2024). DOI: 10.1016/j.isci.2024.109881

In new research, investigators at Massachusetts General Hospital (MGH) show that the 100-year-old Bacillus Calmette-Guérin (BCG) vaccine, originally developed to prevent tuberculosis, protects individuals with type 1 diabetes from severe COVID-19 disease and other infectious diseases.

Two back-to-back randomized double-blinded placebo-controlled trials found that the BCG vaccine provided continuous protection for nearly the entire COVID-19 pandemic in the US, regardless of the viral variant.

"Individuals with type 1 diabetes are highly susceptible to [infectious diseases](#) and had worse outcomes when they were infected with the SARS-CoV-2 virus," said senior author Denise Faustman, MD, Ph.D., director of the Immunobiology Laboratory at MGH and an Associate Professor of Medicine at Harvard Medical School.

"Published data from other investigators show mRNA COVID-19 vaccines are not very effective in this group of vulnerable patients. But we've shown that BCG can protect type 1 diabetics from COVID-19 and other infectious diseases."

The 18-month Phase III trial, [published](#) in *iScience*, was conducted late in the US pandemic when the highly transmissible omicron variant was circulating. A 15-month Phase II trial was conducted early in the pandemic; results of that trial were published in [Cell Reports Medicine](#).

During the COVID-19 pandemic, several international trials tested if BCG as a single shot, or booster, given to previously BCG-vaccinated adults protected them from infection and COVID-19. This research

expanded the large global clinical trial database showing that BCG administered to newborns works as a platform for all infectious disease, maybe for decades. But results from these COVID-19 booster trials in people previously vaccinated with BCG were mixed, with five randomized trials showing efficacy and seven trials showing no benefit.

The MGH Phase II and Phase III clinical trials testing BCG differed from other BCG trials in important ways. Instead of receiving one dose of BCG, participants received five or six doses of a particularly potent strain of BCG vaccine. The US participants were followed for a total of 36 months instead of weeks or months.

"We know that in people who are naïve to BCG vaccine, the off-target effects can take at least two years to achieve full protection," said Faustman. "Giving multiple doses of the vaccine may speed up that process."

And importantly, the US population had never received BCG vaccines, so these [clinical trials](#) were not booster trials.

"The Phase II and Phase III trials conducted at MGH were unique in that they were the only COVID trials in the world in which the study population had never received a BCG vaccine and was never exposed to TB," said Faustman. "Trials conducted in countries where participants had previously received BCG vaccine as newborns or who had previous exposure to tuberculosis may have obscured any benefit from a BCG booster."

The MGH trials enrolled 141 participants with type 1 diabetes; 93 people in the treatment group received five or six doses of BCG vaccine and the 48 individuals in the placebo group received sham vaccine and were followed for 36 months to capture diverse COVID-19 genetic variants and many infectious disease exposures.

During the earlier Phase II trial (January 2020 to April 2021) when the virus was more lethal but less transmissible, the BCG vaccine's efficacy was 92%, comparable to the efficacy of the Pfizer and Moderna COVID-19 vaccines in healthy adults.

Over the full 34 months of the US COVID-19 pandemic, the BCG vaccine had a significant efficacy of 54.3%. The investigators also found that the BCG-treated participants had lower rates of viral, bacterial, and fungal infections as well as COVID-19 disease itself.

The BCG vaccine confers an immunity that likely lasts decades, a clear advantage to the COVID-19 vaccine and vaccines against other infectious diseases, such as influenza, where the duration of effectiveness is only two or three months.

"The BCG vaccine offers the prospect of near-lifelong protection against every variant of COVID-19, the flu, [respiratory syncytial virus](#), and other infectious diseases," said Faustman.

Some of the BCG-treated participants also received the commercially available COVID-19 vaccines during the Phase III trial. The investigators observed that the Pfizer, Moderna, and Johnson & Johnson vaccines did not protect people with type 1 diabetes against COVID-19.

"Our study showed that the BCG vaccine neither increased the efficacy of the COVID-19 vaccine, nor was it harmful to those who received the COVID-19 vaccine," said Faustman. "As the pandemic continues to evolve it will be interesting to see if we can work with the FDA to allow access to BCG vaccine for type 1 diabetics, who appear to be particularly at risk for all infectious diseases."

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More information: Late in the US pandemic, multi-dose BCG vaccines protect against COVID-19 and infectious diseases, *iScience* (2024). DOI: [10.1016/j.isci.2024.109881](https://doi.org/10.1016/j.isci.2024.109881).

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