

Study finds potential mechanism for BCG vaccine reversal of type 1 diabetes

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Interim results from a FDA-approved clinical trial testing the generic vaccine bacillus Calmette-Guérin (BCG) to reverse advanced type 1 diabetes are being presented at the 75th Scientific Sessions of the American Diabetes Association. The data demonstrate a potential new mechanism by which the BCG vaccine may restore the proper immune response to the insulin-secreting islet cells of the pancreas. Presented by Denise Faustman, MD, PhD, director of the Massachusetts General Hospital Immunobiology Laboratory and principal investigator of the trial, the findings suggest that BCG may induce a permanent increase in expression of genes that restore the beneficial regulatory T cells (Tregs) that prevent the immune system from attacking the body's own tissue.

"Many groups are looking at the ability of BCG vaccination to reverse autoimmunity," says Faustman, who is an associate professor of Medicine at Harvard Medical School. "We and other global efforts have known for some time that restoring beneficial Treg cells might halt the abnormal self-reactivity in type 1 [diabetes](#) and other autoimmune diseases, but therapies to restore this immune balance have not achieved long-lasting results. The discovery that BCG restores Tregs through epigenetics - a process that modulates whether or not genes are expressed - is exciting. This now provides a better idea of how BCG vaccination appears to work by powerfully modulating Treg induction and resetting the immune system to halt the underlying cause of the disease."

Type 1 diabetes is an autoimmune disease characterized by the

destruction of islets by autoreactive T cells, which mistakenly attack islets as if they were an infection. Tregs are the immune system's "brakes" that normally prevent misdirected attacks against tissues without dampening the entire system. Several research groups have suggested methods for introducing or expanding Tregs in patients with type 1 diabetes, but to date no therapies have been approved.

Best known for its role in tuberculosis prevention, the BCG vaccine is based on a harmless strain of bacteria related to the one that causes tuberculosis. A generic drug with over 100 years of clinical use and safety data, BCG is currently approved by the FDA for vaccination against tuberculosis and for the treatment of bladder cancer. Multiple international studies are currently investigating the potential of repeat BCG vaccinations to prevent and reverse autoimmune diseases including type 1 diabetes and multiple sclerosis.

"BCG is interesting because it brings into play so many areas of immunology that we as a community have been looking at for decades, including Tregs and the hygiene hypothesis," says Faustman. "Repeat BCG vaccination appears to permanently turn on signature Treg genes, and the vaccine's beneficial effect on host immune response recapitulates decades of human co-evolution with mycobacteria, a relationship that has been lost with modern eating and living habits. It is incredible that a safe and inexpensive [vaccine](#) may be the key to stopping these terrible diseases."

Faustman's research team was the first group to document reversal of advanced type 1 diabetes in mice and subsequently completed a successful phase I human clinical trial of BCG vaccination. The five-year, 150-person, [phase II trial](#) is investigating whether repeat BCG vaccination can clinically improve type 1 diabetes in adults with existing disease and is almost fully enrolled. Details on the trial and enrollment are available at: <https://clinicaltrials.gov/ct2/show/NCT02081326>.

Long-term follow-up data from the phase I trial will be published later this year. The phase II trial is entirely funded by private philanthropy from individuals and family foundations. Additional information about the clinical trial, including information for potential participants and financial supporters, is available at <http://www.faustmanlab.org> or by emailing DiabetesTrial@partners.org.

Provided by Massachusetts General Hospital

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