



Now Recruiting: BCG Vaccinations for Pediatric Type 1 Diabetes

Researchers at Massachusetts General Hospital (MGH) are seeking **pediatric** patients with **type 1 diabetes** to participate in a clinical trial to assess the effects of Bacillus Calmette-Guérin (BCG) vaccination on blood sugar control.

BACKGROUND:

Introduced in 1921, BCG is a tuberculosis vaccine considered to be **extremely safe**, is on the World Health Organization's List of Essential Medicines, and administered to roughly 100 million infants per year globally. It is not routinely given in the United States due to the low risk of tuberculosis infection. BCG is also one of the most affordable medicines, costing less than a dollar per dose in many parts of the world.

In a randomized double-blind Phase I adult clinical trial conducted at MGH, two injections of BCG showed significant efficacy in **lowering HbA1c** in established type 1 diabetes. A similar open-label trial confirmed the promising data. The vaccine lowered HbA1c without a high incidence of hypoglycemia, resulting in a **lower insulin requirement** and **easier diabetes management**. BCG is currently being studied in a randomized double-blind Phase 2 adult trial.

Global studies suggest BCG protects from other autoimmune diseases such as multiple sclerosis. It is also a highly effective treatment for bladder cancer. In addition to tuberculosis, BCG protects humans from other viral and bacterial infections.

NEW PEDIATRIC TRIAL:

This 5-year randomized double-blind placebo-controlled Phase 2 pediatric trial will study the potential of two doses of the BCG vaccine as a treatment for type 1 diabetes. We will characterize the efficacy of BCG in lowering HbA1c values as well as important markers of type 1 diabetes including c-peptide and insulin use.

A complete list of inclusion and exclusion criteria can be found on clinicaltrials.gov (NCT05180591 & NCT05866536)

HOW TO GET INVOLVED IN OUR TRIALS AND LEARN MORE:

First Step

Join: <https://redcap.link/faustmanimmunobiologylab>

All are encouraged to sign up! You will receive an email directly from us after you complete your registration.

Please Contact:

Email: diabetestrial@partners.org

Phone: 617-726-4084

Website: www.faustmanlab.org

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2. Ristori, G et al. Use of Bacillus Calmette Guerin (BCG) in multiple sclerosis. **Neurology**. 1999; 53:588-1589.
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4. Faustman DL et al. Multiple BCG vaccinations for prevention of COVID-19 and other infectious diseases in Type 1 diabetes. **Cell Rep Med**. 2022; 3:100728.