



Steven Arnold, M.D.
Massachusetts General Hospital
Boston, Massachusetts

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BCG Immunization effects on Biomarkers of Inflammation/Immune Response and Alzheimer's Disease

This early phase Pilot study will evaluate whether a vaccination may impact brain inflammation in Alzheimer's.

PI

- M.D., Boston University, 1983
- Translational Neurology Head of the Interdisciplinary Brain Center at Mass General, Harvard Medical School, 2015
- Authored over 250 scientific articles, reviews and chapters

STUDY

- CADRO category: Translational Research & Clinical Interventions

Background

Microglia are the primary immune cells of the brain. Microglia help maintain healthy nerve cells in the brain. Individuals with Alzheimer's typically experience brain inflammation caused by dysregulation of the immune system, including increased activity of microglia, which can damage nerve cells. Researchers have been studying ways to reduce brain inflammation.

Studies have shown that the BCG (Bacillus Calmette-Guerin) vaccination in genetically engineered Alzheimer's-like animal models may improve cognition and behavior. BCG vaccination is also used as a treatment in bladder cancer and is being explored in other diseases such as multiple sclerosis and type 1 diabetes. Past studies by Dr. Steven Arnold and colleagues as well as other research groups have found that using the BCG vaccine to treat bladder cancer may result in a 2-4-fold decrease in the occurrence of dementia in these individuals. Dr. Arnold's team will specifically test the impact of the BCG vaccine in brain inflammation in Alzheimer's.

Research Plan

Building on their prior work, Dr. Arnold and colleagues will evaluate the impact of the BCG vaccine on 30 individuals with mild cognitive impairment (a condition of subtle memory loss, due to Alzheimer's disease) or early stage Alzheimer's. Participants in the study will receive either the BCG vaccine or a placebo (not the actual drug but an inactive substance that has no benefits and also no risk for the participant).

The researchers will evaluate the impact of the drug in the study participants by measuring proteins in blood samples and cerebrospinal fluid (a biological fluid sample found in the brain and spinal cord). The proteins will serve as biological markers (biomarkers) to help the researchers track inflammation and levels of beta-amyloid plaques and tau tangles, the hallmark brain changes observed in Alzheimer's. They will also measure any brain changes (such as the volume of brain) with Magnetic Resonance Imaging (MRI) brain scans and cognitive tests over the course of the trial.

Impact

This clinical trial represents an important step to determine whether the BCG vaccine could reduce brain inflammation in Alzheimer's. If successful, the results of this work could lead to future large-scale clinical trials to evaluate whether BCG will be able to delay or stop progression of mild cognitive impairment and Alzheimer's.

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