



Alireza Faridar, M.D.
The Methodist Hospital Research Institute
 Houston, TX

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Regulatory T cells as a novel therapeutic target in Alzheimer’s Disease

This Phase I/Phase 2a trial will examine whether a chemical compound could impact brain inflammation as a treatment for Alzheimer’s.

Background

The immune system is a complex system in the brain that serves to maintain healthy nerve cells in the brain. Individuals with Alzheimer’s have increased levels of brain inflammation. One of the less understood mechanisms is the role that one group of immune cells called regulatory T cells (or Tregs) may play in brain inflammation. Past studies show that Tregs may play a protective role in suppressing brain inflammation. Past work by Dr. Alireza Faridar and colleagues have shown that in individuals with Alzheimer’s, Tregs may lose the ability to block inflammation caused by the immune system. Preliminary studies conducted by Dr. Faridar’s team in a laboratory dish and genetically engineered Alzheimer’s-like mice models have shown that a compound called Interleukin-2 (IL-2) could enhance the activity of Tregs and restore their function of suppressing brain inflammation. IL-2 has been approved by the U.S. Food and Drug Administration as a treatment for skin cancer. Dr. Faridar’s team will be exploring its use as a potential treatment for Alzheimer’s. In an ongoing Phase 1 clinical trial the researchers have administered IL-2 in a small number of individuals with mild to moderate Alzheimer’s. The preliminary results show that IL-2 could be safe and tolerated by these participants. Additionally, the researchers observed that IL-2 may have remarkably improved cognitive function in these participants.

PI

- M.D., Tehran University of Medical Sciences, Iran, 2008
- Assistant Professor of neurology, Houston Methodist Hospital, TX 2018-

STUDY

- CADRO category: Translational Research & Clinical Interventions

Research Plan

Building on their preliminary results, Dr. Faridar and colleagues will expand their Phase 1 study results to a larger group of participants to evaluate safety, tolerability and efficacy of the potential therapy.

The researchers will conduct a Phase 2a clinical trial in 40 individuals with mild to moderate Alzheimer’s. Participants in this study will receive a placebo (not the actual drug but an inactive substance that has no risk for the participant) or low dose of IL-2. The researchers will monitor the safety and tolerability of IL2 in the participants. In addition, the researchers will evaluate

the impact of IL-2 in the study participants by measuring proteins (beta-amyloid and tau and biomarkers of inflammation) in the cerebrospinal fluid (a biological fluid sample found in the brain and spinal cord). These 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. In addition, the researchers will also evaluate the impact of IL-2 on the cognitive function of the participants.

Dr. Faridar proposes that IL-2 may reduce brain inflammation, slow the progression of accumulation of tau in the brain and could thereby prevent the progression of Alzheimer's.

Impact

If successful, the study results may give rise to larger clinical trials and pave the way to evaluate this approach as a potential therapy to delay the progression of Alzheimer's.

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