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The PIONEER study: A Phase 2 trial of T3D-959 in Alzheimer's Subjects

This Phase 2 clinical trial will evaluate whether a chemical compound can alter brain energy levels to stop or reverse the progression of Alzheimer's.

PI

- Ph.D., Medical Microbiology, University of Vermont College of Medicine, 1982
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STUDY

- CADRO category: Translational Research & Clinical Interventions

Background

The brain requires more energy to function properly than any other organ in the body and glucose (sugar) is the major source of this energy. If the brain loses its ability to effectively process and convert sugar to energy (metabolism), the brain's ability to function is impaired. This may contribute to Alzheimer's-related brain changes, such as the formation of beta-amyloid plaques and tau tangles.

Dr. John Didsbury and colleagues will test whether a new chemical compound has the potential to correct the dysfunctional sugar metabolism seen in the brains of individuals with Alzheimer's to possibly slow, stop or reverse the progression of disease. In preliminary results, the researchers observed their compound impacted brain sugar metabolism.

Research Plan

Leveraging their initial findings, Dr. Didsbury and colleagues will conduct a Phase II clinical trial called the PIONEER study [Prospective therapy to Inhibit and Overcome Alzheimer's Disease Neurodegeneration via Brain EnErgetics and Metabolism Restoration]. This study will test the safety and tolerability of their compound in 256 individuals with mild to moderate Alzheimer's. Participants in the study will receive either a once-daily dose of the drug or a placebo (not the actual drug but an inactive substance) for 24 weeks.

In addition to monitoring the safety of the compound, the researchers will perform cognitive tests and collect blood samples from the participants. Using these measures, the researchers will study changes in cognition and brain function (such as metabolism) as well as biological markers (biomarkers) associated with Alzheimer's (such as levels of beta-amyloid and tau in the blood). Dr. Didsbury's team will

use these results to evaluate the impact of their compound on cognitive changes and brain function in the participants.

Impact

This study will test whether the new chemical compound might improve and enhance brain energy metabolism and thereby prevent or reduce the progression of Alzheimer's.

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