

UM Neurologists Test New Drug to Potentially Slow Progression of Alzheimer's Disease

Neurologists and researchers with the University of Miami Miller School of Medicine and the University of Miami Health System have begun screening study participants for a new national Alzheimer's disease (AD) clinical study to evaluate the potential benefits of an investigational medicine for people with mild to moderate Alzheimer's.



The Phase 2 study, called T2 Protect AD, is evaluating the investigational drug troriluzole (BHV-4157), which may have the potential to protect against, slow down, and eventually improve memory and thinking problems that increase as Alzheimer's disease progresses. Troriluzole is a drug that modulates glutamate, protecting against neuron loss. Glutamate problems in the brain can lead to brain cell dysfunction and disease, including Alzheimer's disease.

"We are hoping this drug truly makes a difference in slowing progression of this illness," said Bernard S. Baumel, M.D., assistant professor of neurology, interim chief of the Cognitive Disorders Division, and director of memory disorders clinical trials. "It's a unique compound that takes a different approach than most recent drugs. Riluzole has shown efficacy in ALS patients, and the prodrug now offers the possibility of helping those with Alzheimer's, and with fewer side effects."

Doctors at UM's memory program are now seeking eligible participants for the T2 Protect AD study. To enroll in T2 Protect AD, participants must be between age 50 and 85, diagnosed with mild to moderate Alzheimer's disease, and already being treated with Alzheimer's medications for at least three months. Participants must have a study partner who has regular contact with the clinical trial candidate and is able to attend study visits.

Study Overview

The T2 Protect AD Study is a national, multi-site randomized, controlled clinical study to evaluate troriluzole in people with mild to moderate AD. The study is designed to determine if troriluzole can protect against, slow down, and potentially improve memory and thinking problems that increase as AD progresses.



Participants are enrolled in the study for 48 weeks



Enroll 292 participants at 30+ medical and AD specialty centers throughout U.S.



Participants are randomized one-to-one on troriluzole or placebo and take one pill one time per day



Study participants visit the study clinic nine times after successfully screening for the trial



At the beginning and end of the study, participants have a brain scan using magnetic resonance imaging (MRI)



The study will measure if the drug can slow down memory loss and improve thinking skills in people with AD

Troriluzole is a prodrug of riluzole, a drug first approved by the Food and Drug Administration in 1995 to slightly slow disease progression in patients with Amyotrophic Lateral Sclerosis (ALS).

A prodrug is an inactive medication that changes into a drug after ingestion. When a person takes troriluzole, the body converts it into the active drug riluzole. This means the prodrug troriluzole can be taken once a day, while riluzole is administered twice a day. Unlike riluzole, patients do not need to fast before and after taking troriluzole, and troriluzole has potential for better safety and tolerability than riluzole.

The Miller School is one of more than 30 sites in the U.S. participating in the T2 Protect AD study. The study is sponsored by New Haven-based Biohaven Pharmaceutical Holding Company Ltd., and is coordinated by the Alzheimer's Disease Cooperative Study, a large clinical research consortium based at the University of California, San Diego.

The T2 Protect AD trial comes at a time when Alzheimer's research is focused on earlier stages of the disease and there are not as many clinical trials for people already diagnosed with Alzheimer's. "Simply put, we need to identify more and better treatments for the millions of people already diagnosed with

Alzheimer’s disease, and the T2 Protect Study is designed for that population,” said Dr. Baumel.

For more information about participating in the T2 Protect AD study at the University of Miami, call (305) 243-0184 or visit [T2 Protect AD](#).