New clinical study focuses on investigational treatment to reduce impact of key protein from the brain

Published on October 12, 2015 at 9:01 AM

The Nantz National Alzheimer Center at Houston Methodist Hospital is part of a landmark clinical trial that looks at removing a key protein from the brain to prevent memory loss at least a decade before symptoms are noticed in healthy older adults.

The national trial is focused on an investigational treatment to reduce the impact of the protein beta amyloid. The A4 study, also known as the Anti-Amyloid Treatment in Asymptomatic Alzheimer's study, is for individuals ages 65 to 85 who are deemed at risk for Alzheimer's disease related memory loss, but who have not yet shown signs of the disease.

Using positron emission tomography (PET scans), researchers and clinicians have found that beta amyloid begins forming plaques in the brains of people with Alzheimer's disease 10-20 years before the initial symptoms of the disease. Scientists believe the accumulation of beta amyloid may play a key role in the eventual development of Alzheimer's-related memory loss, by inducing excess production of an abnormal form of the important brain protein, tau.

The investigational drug used in the A4 study is the mono-clonal antibody solanezumab, which targets excess amyloid in the brain. The goal of this study is to learn whether solanezumab will delay cognitive decline and memory loss symptoms in patients who have not yet been diagnosed by slowing possible Alzheimer's related damage in the brain.

Joseph Masdeu, M.D., and his team at the Nantz National Alzheimer Center in Houston is one of a handful of study sites to also scan patients for abnormal tau, which forms tangles of fibers that likely destroy nerve cells and spread brain damage.

"It is encouraging to be able to detect excess beta amyloid with PET technology in people predisposed to Alzheimer's and then try to lower the amyloid levels with solanezumab," said Masdeu, principal investigator of the A4 study at Houston Methodist Hospital and director of the Nantz National Alzheimer Center. "However, there appears to be a point in the development of Alzheimer's where removing beta amyloid does not reverse or stop disease progression because too much abnormal tau has been generated by then. That is why it is important to use PET to measure the amount of abnormal brain tau as well."

Masdeu was the first physician-scientist to detect an early imaging feature of Alzheimer's disease and has long focused on neuroimaging's role in determining the brain changes that underlie the memory and language problems characteristic of Alzheimer's disease.

According to the Alzheimer's Association, someone in the United States develops Alzheimer's every 67 seconds and 16 million Americans are expected to be affected by the disease by 2050. In 2014, Alzheimer's caregivers provided an estimated 17.9 billion hours of unpaid care valued at more than \$217.7 billion.

"Among the major causes of death in the United States, Alzheimer's is the only one that we currently cannot prevent or cure," said Masdeu. "We hope that slowing the onset of Alzheimer's will help patients hold on until a prevention or cure can be found."

To qualify for the study, patients must be between the ages 65 and 85 and have a study partner who is willing to participate as a source of information and has at least weekly contact with the participant. Neuroimaging testing using a PET scan will determine whether abnormal beta amyloid deposits are present in the brain. If so, study patients will be randomized to either the investigational treatment or a placebo group.

Approximately 1,000 adults are expected to participate in more than 60 sites across the United States, Canada and Australia. Masdeu expects to enroll 30 people at Houston Methodist Hospital. The three-year study is funded by the National Institute on Aging, Eli Lilly and Company, and several philanthropic organizations. The A4 study is coordinated by the Alzheimer's Disease Cooperative Study.

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Source:

Houston Methodist Hospital