Researchers testing gene therapy for Alzheimer's disease

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University Hospitals Case Medical Center is one of 12 sites conducting the first Phase 2 clinical trial of a gene therapy for Alzheimer's disease (AD). The study uses a viral-based gene transfer system called CERE-110, which is designed to deliver nerve growth factor (NGF) into the brain. University Hospitals (UH) is the only site in the Midwest for the study.

The study is sponsored by a contract to Case Western Reserve University from the Alzheimer's Disease Cooperative Study (ADCS) through a grant from the National Institute on Aging in association with Ceregene, Inc., which developed and will provide the active agent CERE-110.

NGF is a naturally occurring protein that may prevent nerve cells in the brain from dying and may help these cells function better. During the study, CERE-110 will be injected by a neurosurgeon into the nucleus basalis of Meynert, an area of the brain where nerve cells die in patients with AD.

"A small study in humans showed that CERE-110 was generally safe and well-tolerated," said Alan J. Lerner, M.D., principal investigator of the Cleveland site, director of the UH Neurological Institute Memory and Cognition Center, and a professor of neurology at the Case Western Reserve University School of Medicine.

The Phase 2 study will evaluate whether the therapy is safe for a larger group of patients and whether it helps the symptoms of AD. In total, 50

patients will be enrolled throughout the United States and UH aims to enroll at least five patients in this study.

"Should the clinical development of this therapy be successful, CERE-110 could offer the possibility of delaying the course of Alzheimer's disease, a real improvement over existing therapies," said Dr. Lerner. "This would not be a cure for AD, but a way of slowing it down."

Participants in the Phase 2 study will be randomly placed into one of two treatment groups, with half of the subjects receiving CERE-110 and the other half receiving placebo surgery. At the completion of the trial, subjects in the placebo arm may have the opportunity to receive the active treatment if the product seems safe and effective.

More information: To be eligible for this study, participants must have mild to moderate AD and be in good health. For a more complete list of eligibility and exclusion requirements, please see the Web site: www.alzheimers.org/clinicaltri … c.asp?PrimaryKey=308 Participants will be screened to determine if they are eligible for the study.

Provided by University Hospitals Case Medical Center