Gammaglobulin Treatment May Slow Alzheimer's Disease

UC San Diego Health System Seeking Participants for Nationwide Clinical Trial

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Researchers at the University of California, San Diego Alzheimer's program have begun a Phase III clinical trial testing a new approach to slowing down the progression of Alzheimer's disease using Intravenous Immune Globulin (IVIg), also known as gammaglobulin. IVIg has been used to treat primary immunodeficiency disorders for more than 20 years, but is not currently approved for treating Alzheimer's, one of the leading forms of dementia.

The Phase III clinical trial is being led by Michael Rafii, MD, PhD, assistant professor of neurosciences at the UC San Diego School of Medicine and associate medical director of the Alzheimer's Disease Cooperative Study (ADCS), a nationwide consortium of institutions, based at UC San Diego and funded by the National Institute on Aging to spearhead clinical trials in the disease. This study expands on promising results of a Phase II trial and is part of the final phase in studying IVIg as a potential treatment for Alzheimer's before seeking regulatory approval.

"Initial research in experimental models and patients suggest that IVIg, which contains naturally occurring human anti-amyloid antibodies, will defend the brain of Alzheimer's patients against the damaging effects of beta amyloid," said Rafii. "If it does, giving IVIg to patients with mild to moderate Alzheimer's may potentially slow the rate of progression of the disease."

One of the hallmarks of Alzheimer's pathology is an abundance of beta-amyloid plaque, thick deposits of proteins in the brain that are believed to play a role in nerve cell degeneration. While it is not yet known if beta amyloid plaques cause or are a byproduct of the disease, scientists are interested in finding ways to reduce the toxic effects of beta amyloid in the brain. The GAP (Gammaglobulin Alzheimer's Partnership) Study will examine the safety and effectiveness of utilizing IVIg to neutralize or eliminate toxic forms of beta amyloid.

The GAP trial is a double-blind, placebo-controlled study in which two-thirds of participants will receive IVIg and one-third will receive placebo. It will last up to 82 weeks. Thirty-six sites around the country are recruiting 360 participants between the ages of 50 and 89 who have been diagnosed with mild to moderate Alzheimer's disease and who have a study partner (spouse, child, sibling or friend) in contact with them 10 hours a week or more.

"In our initial studies in AD patients, IVIg provided significant cognitive benefits, improved brain metabolism and reduced beta amyloid levels in the spinal fluid," said Norman Relkin, MD, Project Director and Director of the Weill Cornell Alzheimer's Disease and Memory Disorders Program. In a Phase II trial at Weill Cornell, Relkin reported that participants undergoing several months of continuous IVIg therapy also demonstrated improvement in their daily activities. He added, "These findings, as well as IVIg's long-established record of safe use for treating other diseases, provide a strong rationale for further study in AD patients on a larger scale."

The research is jointly funded by Baxter International Inc. and the National Institute on Aging. For additional information on the trial, contact Elizabeth Ortega at UC San Diego at 858-677-1567 or visit www.adcs.org/studies/IGIV

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