

Scientists to test gammaglobulin treatment for Alzheimer's disease

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Researchers from the Memory and Cognition Center at University Hospitals Case Medical Center will begin testing an intriguing new approach to slowing down the progression of Alzheimer's Disease (AD) using Intravenous Immune Globulin (IGIV), also known as gammaglobulin. IGIV is traditionally used to treat primary immunodeficiency disorders, but is not currently approved for treating AD, which is one of the leading causes of dementia in the elderly.

Initial research in experimental models and patients suggests that immunotherapy targeting beta amyloid (the protein that forms the core of plaques in the brain) may provide a more effective way to treat AD. [Antibodies](#) that bind to beta amyloid are present in IGIV, which is made from the blood of several thousand healthy adults.

One of the hallmarks of AD pathology is an abundance of beta-amyloid deposits in the brain. While it is not yet known if beta amyloid plaques cause AD or are a byproduct of the disease, scientists are interested in finding ways to reduce the toxic effects of beta amyloid on the brain. Antibodies against beta amyloid may do so by binding to toxic forms of beta amyloid, thereby neutralizing them and/or promoting their elimination.

"We are investigating whether IGIV, which contains naturally occurring human anti-amyloid antibodies, will defend the brain of AD patients against the damaging effects of beta amyloid. If it does, giving IGIV to patients with mild to moderate Alzheimer's may potentially slow the rate

of progression of the disease," says Alan Lerner, M.D., principal investigator for the study in Cleveland and director of the Memory and Cognition Center.

"In our initial studies in AD patients, IGIV provided significant cognitive benefits, improved brain metabolism and reduced beta amyloid levels in the spinal fluid," says Norman Relkin, M.D., project director and director of the Weill Cornell Alzheimer's Disease and Memory Disorders Program. In a Phase II trial at Weill Cornell, Dr. Relkin reported that participants undergoing several months of continuous IGIV therapy also demonstrated improvement in their activities of daily living. He added, "These findings, as well as IGIV'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 GAP (Gammaglobulin Alzheimer's Partnership) Study will examine the safety, effectiveness and tolerability of IGIV in patients with mild to moderate AD. GAP is recruiting 360 participants at 36 sites nationwide. This large Phase III clinical trial expands on earlier testing, is one of two Phase III trials and is part of the final phase in studying IGIV as a potential treatment for AD before seeking regulatory approval.

The trial is being conducted by the Alzheimer's Disease Cooperative Study (ADCS), a nationwide consortium of research centers and clinics coordinated by the University of California at San Diego and directed by Paul Aisen, M.D.

"As many as five million Americans may be afflicted now and with the numbers growing rapidly, ADCS clinical trials such as the GAP study are essential to finding new and more effective treatments for [Alzheimer's disease](#)," Aisen commented.

Source: University Hospitals Case Medical Center

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