

Small study: Drug may help stabilize Alzheimer's

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This Sunday, July 8, 2012 file photo shows boxes of Gammagard, a treatment that is being tested for Alzheimer's disease, in the home of a patient in New York. For the first time, researchers are reporting that a treatment might help stabilize Alzheimer's disease for as much as three years, but the evidence is weak and only in four patients. Gammagard is a collection of antibodies from pooled blood donations given as infusions every two weeks. These antibodies may help clear the sticky plaque that clogs patients' brains. The results were discussed Tuesday, July 17, 2012 at an Alzheimer's conference in Vancouver, British Columbia, Canada. (AP Photo/Seth Wenig)

For the first time, researchers are reporting that a treatment might help stabilize Alzheimer's disease for as much as three years, although the evidence is weak and found in only four patients.

The drug is Gammagard, made by Baxter International Inc. Doctors say that four patients who have been receiving the highest dose for three

years showed no decline on memory and cognition tests. A dozen others on different doses or shorter treatment times didn't fare as well.

This study was far too small to prove the treatment works, but a more rigorous one involving 400 patients will give results within a year.

Still, the findings from the small study encouraged doctors at the Alzheimer's Association International Conference in Vancouver, British Columbia, where they were presented on Tuesday.

"It's tantalizing. If you were to pick out four people with Alzheimer's disease, the likelihood that they would perform the same on standardized tests three years later is very, very tiny," said William Thies, the association's scientific director.

People typically go from diagnosis to death in about eight years, so to be stable for three years "is a long time," he said. "We shouldn't get euphoric and we shouldn't get unreasonable enthusiasm, but this is a positive piece of data."

The need for an effective treatment is huge: About 35 million people worldwide have dementia, and Alzheimer's is the most common type. In the U.S., about 5 million have Alzheimer's. Current medicines such as Aricept and Namenda just temporarily ease symptoms. There is no known cure.

Gammagard is intravenous immune globulin, or IVIG — multiple, natural antibodies culled from donated blood. Half a dozen companies already sell IVIG to treat immune system and blood disorders. These antibodies may help remove amyloid, the sticky plaque that clogs patients' brains, sapping memory and ability to think.

On Tuesday, Dr. Norman Relkin, head of a memory disorders program

at New York-Presbyterian Hospital/Weill Cornell Medical Center, gave three-year follow-up results on 16 of 24 patients in an earlier study of Gammagard aimed at finding the right dose to use in the larger study. The other eight are no longer being followed, and at least some of them have died.

After the early study ended, some participants were kept on Gammagard and some who had been receiving dummy infusions were switched to Gammagard.

Relkin found:



In this Sunday, July 8, 2012 photo, Jason and Karin Marder pose for a picture in their home in New York. Jason Marder, who turned 70 on Tuesday, July 10, 2012, was diagnosed with Alzheimer's more than eight years ago. In the roughly five years that her husband has taken Gammagard, "there has been decline" in his health but it is very minimal and the kind of slowing down you might expect from ordinary aging, she said. "He travels the subways, he does things that you and I do. And our quality of life together is what's most important." (AP Photo/Seth Wenig)

—As a group, the 11 patients started on various doses of Gammagard

fared better than the five started on dummy infusions.

—The five given dummy treatments declined more slowly after they were switched to Gammagard.

—All four participants originally given the highest dose and kept on that dose for three years showed no decline in cognition.

"To have all four not progress was very eye-opening," Relkin said. Even a single patient who doesn't decline over three years is unusual, he said.

"When I see that in clinical practice, I start to question whether the person has Alzheimer's disease," but all of these study participants were verified by advanced testing to have it, he said.

Jason Marder is among them. The New York City man, who turned 70 last week, was diagnosed with Alzheimer's more than eight years ago and continues to get Gammagard infusions every two weeks from a visiting nurse at home.

"I feel that I haven't gone down, and that's good," he said in a recent interview. "I feel good. I'm very independent."

His wife, Karin Marder, said: "He has slowed down, no question about it. His walk is a little slower but that could also have a lot to do with age. He's still the Jason that I married. He's still there. We still have a wonderful relationship together. I'm grateful for every day that he's independent."

Other doctors warned against over-optimism on these early results. Many previous drugs looked good until tested in large, definitive studies.

"That's the only way we can get data we can really rely on," said Dr.

Reisa Sperling, a neurologist at Harvard-affiliated Brigham and Women's Hospital in Boston.

Dr. Ronald Petersen, director of the Mayo Clinic's Alzheimer's Disease Research Center, agreed.

"The concern with this study is there has been attrition over time," so the people left in the study are the ones who did well whereas others may have died, he said. These early results "will just whet our appetites" for the bigger study's results, he said.

That 400-patient study, headed by Relkin, will end late this year, and results are expected early next year. Treating Alzheimer's with IVIG would cost \$2,000 to \$5,000 every two weeks, depending on the patient's weight, he estimated.

"We want to make clear that this is not an approved treatment as yet and we're not making any sensational claims," Relkin said.

Two other experimental Alzheimer's drugs are in late-stage studies that just ended; results are being analyzed now. They are:

—Bapineuzumab, by Pfizer Inc. and Johnson & Johnson's Janssen Alzheimer Immunotherapy unit.

—Solanezumab, by Eli Lilly & Co.

On Tuesday, J&J announced that results of two studies testing bapineuzumab will be presented at a neurology conference in Sweden in September. The main result is expected to be announced before then, as soon as it is known.

More information:

Alzheimer's info: www.alzheimers.gov

Alzheimer's Association: www.alz.org

Alzheimer's Association International Conference:

www.alz.org/aaic/overview.asp

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