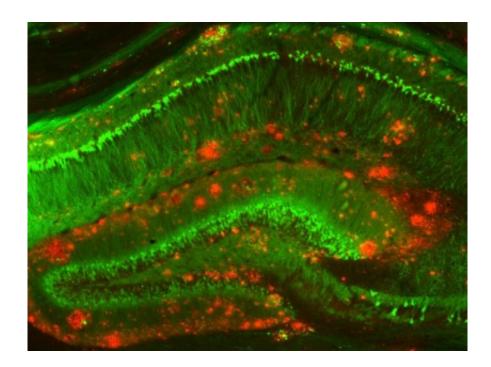


## New Alzheimer's study aims to delay or prevent symptoms

June 17 2016, by Eddie North-Hager



In a person with Alzheimer's, harmful amyloid beta clusters (red) build up among neurons (green) in a memory-related area of the brain. Credit: Photo/Strittmatter Laboratory, Yale University

USC researchers announced Tuesday they will test a promising drug aimed at preventing or delaying the symptoms of Alzheimer's disease.

The international study, jointly managed by the USC Alzheimer's Therapeutic Research Institute (ATRI) and Janssen Research & Development, will test Janssen's BACE inhibitors in people who are



currently showing no symptoms.

The investigational drug aims to block an enzyme involved in the generation of the amyloid peptide, a toxic molecule believed to play an essential role in causing Alzheimer's.

"We are now looking at the stage of Alzheimer's that precedes even mild symptoms," said Paul Aisen, founding director of USC ATRI and professor of neurology at the Keck School of Medicine of USC. "It is our view that drugs such as BACE inhibitors may be most effective at the earliest stages of the disease."

USC ATRI's role in the study is funded by a new contract with Janssen. USC ATRI, located in San Diego, and Janssen will provide joint oversight for the study; in addition, ATRI will manage study activities at sites in the United States and Canada. Study sites in other countries will be managed by Quintiles.

"There is a lot of optimism that research may be ushering in a new era in Alzheimer's drug development," said Gary Romano, head of Alzheimer's clinical development at Janssen. "We may be able to treat the disease using interventions before it becomes advanced, much like you treat high cholesterol to mitigate the risk of heart attacks."

## Trial details

This is a phase 2/3 randomized, double-blind, placebo-controlled, parallel group, multicenter study in people across North America, Europe, Japan and Australia who have evidence of brain amyloid accumulation but are asymptomatic.

The trial will recruit individuals who show no outward symptoms and are 60 or older. They will then be tested for amyloid accumulation in the brain and, if positive, will be invited to participate in the study. The



study will assess cognitive performance, along with other measures related to Alzheimer's, over time.

The study will employ a framework created by USC ATRI investigators for testing drugs at the earliest stages of the disease when treatment would be most effective by attacking the driving molecules before substantial damage to the brain has occurred.

It will enroll more than 1,600 people worldwide, including 660 participants at 75 sites in North America who have not experienced any clinical signs of Alzheimer's. Aisen and Reisa Sperling, director of the Center for Alzheimer's Research and Treatment at Harvard Medical School, will be the co-principal investigators of the research.

**More information:** More details about the study can be found at the National Institutes of Health's Clinical Trials website. <a href="mailto:clinicaltrials.gov/ct2/show/study/NCT02569398">clinicaltrials.gov/ct2/show/study/NCT02569398</a>

## Provided by University of Southern California

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