

# UW Health: Groundbreaking phase 3 Alzheimer's clinical trial at UW in need of volunteers

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MADISON, Wis. – The University of Wisconsin School of Medicine and Public Health is recruiting volunteers for a study testing an investigational treatment that aims to help prevent the earliest memory loss due to Alzheimer's disease.

The AHEAD Study is a phase 3 clinical trial, which means this experimental drug's effectiveness will be tested in a larger group of individuals. The trial has already gone through rigorous testing for side effects in research participants in phases 1 and 2 and results showed it was safe to move to phase 3.

The AHEAD Study is the first Alzheimer's disease research study to recruit people as young as 55 years old who are at risk of developing symptoms of Alzheimer's disease as they get older, while using an approach that tailors dose levels of the investigational treatment to study participants' brain amyloid levels. Risk factors include family history of the disease or being 65 years old or older (age increases your risk). The study participant must be cognitively healthy.

The sixth leading cause of death in the United States, Alzheimer's disease is the only disease among the top 10 causes of death that cannot be prevented, cured or slowed. Currently, 120,000 Wisconsinites 65 and older are living with Alzheimer's. Communities of color experience higher incidence of the disease than white communities, yet they remain underrepresented in clinical research.

Dr. Cindy Carlsson, director of the Wisconsin Alzheimer's Institute, and UW Health geriatrician, is the principal investigator of the study location at UW–Madison. “We know that changes in the brains of people with Alzheimer's disease begin up to 20

years before a person notices symptoms, but until now, most clinical trials have included older patients who already have symptoms,” Carlsson said. “By inviting younger participants without symptoms, we hope to help individuals who are at higher risk – such as people with family history – get ahead of the disease with early intervention. We also want to reach diverse communities to learn more about why people of color may be at higher risk of cognitive decline.”

The AHEAD Study consists of two different clinical trials testing the same investigational treatment, known as BAN2401, or lecanemab. BAN2401 is a monoclonal antibody that is thought to either enhance clearance of amyloid or neutralize their toxicity towards brain cells. Amyloid is a protein that builds up in people who can go on to have memory problems and develop Alzheimer’s disease. Participants are enrolled in one of the two trials based on the level of amyloid in their brain.

The AHEAD Study is funded by the National Institutes of Health (NIH) and Eisai Inc., a United States subsidiary of Eisai Co., Ltd., based in Tokyo, and seeks 1,165 participants from North America. The study has more than 100 study locations worldwide, including North America, Japan, Singapore, Australia and Europe.

This clinical trial is a four-year commitment for participants and includes screening visits, blood draws, cognitive testing, PET and MRI scans and physical exams.

If interested in participating please contact: the AHEAD lead study coordinator at UW–Madison, at 608 263-4646 or email: [mcfalk@medicine.wisc.edu](mailto:mcfalk@medicine.wisc.edu).

For more information visit [AHEADstudy.org](http://AHEADstudy.org).