

The A4 Study

A Phase III study of the drug solanezumab

MEMORY CENTER RESEARCH

The Anti-Amyloid Treatment in

Asymptomatic Alzheimer's study (A4 for short), is a clinical research study for older individuals who may be at risk for Alzheimer's disease (AD).

The A4 study is investigating a drug intervention, solanezumab, that may reduce the impact of a protein known as "amyloid" or "beta amyloid" in the brain. Scientists think that elevated amyloid may play a key role in the development of AD-related mental deterioration. The investigational drug used in A4 targets the excess amyloid in the brain with the aim of slowing the memory and related deterioration associated with the development of AD.

Half the participants in the A4 study will receive the investigational drug, and half will receive a "placebo" (non-active agent used for comparison). The drug and the placebo are given by an intravenous infusion.

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## Who may be eligible to participate?

Individuals 65-85 years of age with normal cognition.

**Participants must have a reliable study partner:** a spouse, relative, or friend who knows the participant well and sees him or her often, who will attend some study visits, and who will provide information about the participant during the study.

## Eligibility is determined through a two-stage process. An initial screening visit to determine normal cognition includes:

- A physical/neurological exam
- Medical history
- Medication review
- Collection of blood and urine (a 10-hour fast prior is required)
- Tests of memory and thinking

## If normal cognition is determined, then a second screening visit to measure levels of brain amyloid will include:

- PET scan to measure brain amyloid
- Electrocardiogram (ECG)
- Brain MRI
- Optional Lumbar Puncture

## After the screening, study activity includes:

• Infusion visits every four weeks, for a total of 42 infusion visits over three consecutive years at the Clinical Translational Research Center at the Hospital of the University of Pennsylvania.

• Participants are reimbursed \$32 for each visit.

• Before enrolling, the participant and study partner must read, understand, and sign a formal consent form which fully explains the study.