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PENN MEMORY CENTER RESEARCH

The PEGASUS Study

A Phase II study of the drug AMX0035

The PEGASUS study is a Phase II clinical trial for older individuals with a diagnosis of probable Alzheimer's disease (AD) or mild cognitive impairment due to AD.

The primary objective of this study is to evaluate the safety and tolerability of the study drug, AMX0035. AMX0035 is an investigational drug and is not FDA-approved.

Participants are assigned at random to receive AMX0035 or a placebo (non-active agent used for comparison). The study drug and placebo are both powders that are mixed with water and taken orally.

The study will also measure the effect of the medication on biomarkers (biological markers) associated with neurological damage by assessing cerebrospinal fluid (CSF) from all volunteers.

This data is an invaluable resource for research into treatments for Alzheimer's disease dementia and other dementias.

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Who may be eligible to participate?

Individuals age 55 to 89 with a diagnosis of probable Alzheimer's disease or Mild Cognitive Impairment.

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.

Must be willing and able to complete all assessments and procedures including two MRI scans and two lumbar punctures.

What happens during study visits?

A screening visit, which may be spaced out over two days, will determine eligibility. It includes:

- Physical and neurological exams
- Electrocardiogram (ECG)
- Blood and urine samples
- Tests of memory and thinking
- MRI scan of the brain
- Lumbar puncture

If eligible, you will attend one in-clinic baseline visit and 4 follow-up visits over the course of 24 weeks.

Compensation

Participants will be compensated for time and travel.

Consent

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

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