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P E N N MEMORY CENTER RESEARCH

The Metformin Study

A Phase II Study of a FDA approved drug

Metformin is a FDA approved insulin sensitizer used to treat diabetes. In preliminary trials, Metformin has been shown to stimulate the development of new nerve cells in the areas of the brain responsible for learning and memory. This study will investigate the safety, tolerability, and cognitive effects of the drug on non-diabetic individuals with Mild Cognitive Impairment and early Alzheimer's disease.

It also examines the drug's impact on "biomarkers" of AD by obtaining and analyzing samples of blood, cerebrospinal fluid, and brain MRI.

Participants will continue on their prescribed FDA-approved Alzheimer's medicines while in this study.

Administration of the drug is in pill form. Participants are randomly assigned to receive a low, medium, or high dose of the study drug or placebo. There is a 100% chance of receiving the study drug for at least eight weeks.

For more information, contact Study Coordinator

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Who may be eligible to participate?

Individuals 55-80 years of age with a diagnosis of Mild Cognitive Impairment (MCI) or early Alzheimer's disease who have no history of diabetes mellitus.

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 all study visits, and who will provide information about the participant during the study.

A screening visit (parts of which may be spaced out over two or three non-continguous days) will determine eligibility. It includes:

- A physical/neurological exam
- Medical history
- Medication review
- Electrocardiogram (ECG)
- Collection of blood and urine (a 10-hour fast prior is required)
- Tests of memory and thinking
- Brain MRI
- A sample of cerebrospinal fluid obtained via lumbar puncture (LP) or "spinal tap"

After the screening, study activity includes:

- One "baseline" visit, then five in-clinic visits (one per month for five consecutive months) at the Perelman Center for Advanced Medicine and twelve weekly phone calls.
- Finger stick glucose levels will be monitored for the first three days after each dosage change.
- A LP and MRI at the third visit and a second MRI at visit five.

- *Participants are reimbursed for time and travel: $30 for each study visit, $50 for each MRI, and $100 per LP.*

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