

Assessment of Safety and Feasibility of Exablate Blood-Brain Barrier Disruption for the Treatment of Patients with Mild Cognitive Impairment (MCI) or Mild Alzheimer's Disease (AD) Undergoing Standard of Care Monoclonal Antibody Therapy

Who is this study for?

This study is for people with mild cognitive impairment (MCI) or mild Alzheimer's disease (AD) who have confirmed amyloid pathology.

What is the study about?

We are investigating whether administering aducanumab or lecanemab treatment when the blood-brain barrier is open or disrupted can help the drugs to safely enter the brain, potentially improve treatment outcomes for people with mild cognitive impairment (MCI) or mild Alzheimer's disease (AD). To do this, we will use ultrasound and a contrast agent to temporarily open the blood-brain barrier for a short time. This opening lasts around 24 hours. We want to see if this temporary opening can reduce protein buildup in the brain and allow medications to reach diseased parts of the brain more effectively.

How long does it last?

The length of this study for participants is approximately 5 years.

What is being done?

Participants are asked to complete various exams, including PET/CT, MRI, lumbar puncture, and other clinical assessments to determine their eligibility for the study. Completing all these assessments may take up to 8 hours over one or more days. After participants are deemed eligible and able to safely continue with treatment, they receive an aducanumab or lecanemab infusion followed by blood-brain barrier opening on the same day or within 7 days of the infusion. The procedure is repeated for up to 6 cycles. Each cycle typically lasts 4-5 hours. Additionally, participants will undergo up to 5 PET scans and 2 more lumbar punctures throughout the study as well as other clinical assessments. Following each procedure, participants will spend up to 24 hours in the hospital and will be sent home when the doctor deems it safe. Afterwards, participants are asked to come to WVU for eight or nine visits over the next 5 years for follow-up.