

Placebo-Controlled Efficacy and Safety Trial of Bapineuzumab in Patients with Mild to Moderate Alzheimer's Disease Who are ApoE4 Non-Carriers

Full title: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN115727) in Patients with Mild to Moderate Alzheimer's Disease who are Apolipoprotein E ϵ 4 non-carriers

Objectives: We are recruiting subjects with Alzheimer's disease (AD) to evaluate a new investigational drug named bapineuzumab. Bapineuzumab is an antibody (a type of protein usually produced by white blood cells to destroy other substances in the body). In Alzheimer's disease a protein called amyloid gathers in the brain and is thought to cause symptoms like memory loss and confusion. It is hoped that bapineuzumab will attach to the amyloid protein in the brain and help the body remove it. If the trial we are doing is successful, then the drug may be approved by the U.S. Food and Drug Administration (FDA) for treating AD. Subjects will be randomly assigned to receive the study drug or placebo. Each subject must have a study partner or caregiver who can accompany the subject to the Neurocare Center for Research for 15 visits over the course of 83 weeks.

If you are interested in learning more about this study: Please e-mail Jodi Larkin at jlarkin@neurocareinc.com or call the Neurocare Center for Research at 1-800-958-1218 and ask to speak with a Research Coordinator.

Principal Investigator: Michael P. Biber, MD
Neurocare Center for Research

Phone: 617-796-7766

Fax: 617-658-6288

Contacts: Jodi Larkin, Mary Jane Scofield and Mary Oster

Contact Phone: 1-800-958-1218

Contact Email: jlarkin@neurocareinc.com

Website: <http://www.elan.com>

Sponsor: Elan Pharmaceuticals, Inc. and Wyeth.

Recruitment period: Ongoing

Inclusion criteria: Men and women, 50 to 89 years old, diagnosed with AD and who have a caregiver who visits with them at least five days a week and could

accompany them to the study visits. Subjects must be willing to undergo a simple blood test to determine whether they are ApoE4 carriers.

Exclusion criteria: If the MRI scan, obtained as part of this trial, during the screening visit identifies any other significant abnormality. Current presence of a major psychiatric disorder. History of stroke, seizures or a disorder of the immune system.

Additional assessments will be performed to assess eligibility for the study.

Compensation: Study subject may receive compensation for participation in this study

Time Commitment: There are 15 study visits including Screening visits at Visits 1 and 2. Study Visits 3-15 are 6-7weeks apart.

Date posted: Enter current date.