

## Clinical Trials

### Highlighted trials

Within this issue, we would like to highlight information for families and individuals who are affected by Alzheimer's disease and related dementias and may be interested in learning more about local clinical trials within the northern New Jersey area. In our upcoming issues, we will also highlight information for clinical trials within central and southern New Jersey. The Alzheimer's Association is providing this information as a service to our readers, not as an endorsement of the studies themselves.

**Site:** Neuro Rehab Institute (Mt. Arlington, Hackettstown, Newark, NJ)


**Study:** 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 Ee4 Carriers and Non-Carriers

This study is recruiting patients to participate in a clinical research study investigating a new treatment for Alzheimer's disease. The study is evaluating the efficacy of an intravenously administered drug in patients with mild to moderate dementia of the Alzheimer's type and its potential disease modifying properties. Patients will receive 13 IV treatments over the course of this trial, which will last approximately 18 months. The proposed benefit is to remove and prevent accumulation of the amyloid plaques associated with Alzheimer's disease. The proposed risks known thus far are swelling around the blood vessels in the brain when the plaques are removed, commonly referred to as vasogenic edema, which can be diagnosed by an MRI of the brain.

Participation is completely voluntary and confidential. All care and treatment provided to patients is paid for by the study sponsor.

**Site:** Neurology Group of Bergen County, P.A. (Ridgewood, NJ)

**Study:** A Randomized, Double-Blind, Placebo-Controlled Study Using a Bayesian Adaptive Design to Evaluate the Efficacy and Safety of ABT-089 in Subjects with Mild-to-Moderate Alzheimer's Disease on Stable Doses of Acetylcholinesterase Inhibitors

This is a double-blind, placebo-controlled, dose-ranging study designed to evaluate the safety of ABT-089 in adults aged 55-90 with mild to moderate Alzheimer's disease. They must be on a stable dose of acetylcholinesterase inhibitors 90 days prior to screening. MMSE score must be 12-26 at screening. The patient cannot be taking memantine 90 days prior to screening. The patient cannot have any other neurological disorders i.e. epilepsy, Parkinson's. The patients will be treated for three months. 



**Please Note:** The Alzheimer's Association, Greater New Jersey Chapter provides this information as a service to our readers, not as an endorsement of the studies themselves. Individuals with a diagnosis of Alzheimer's disease or a related dementia and their families need to carefully consider the benefits and/or risks of participating in a clinical trial. Prior to making any decisions, we also encourage you to speak with your physician regarding participation. Every effort is made to provide the most complete and up to date information on local clinical trials. For further information, please call our Helpline at 1.800.883.1180.

| Study   | Location                         | City       | State | Zip   | Phone        | Contact                                |
|---|----------------------------------|------------|-------|-------|--------------|--|
| A Phase 3, 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 Ee4 Carriers (302) or Apolipoprotein Ee4 Non-Carriers (301) | Alzheimer's Research Corporation | Manchester | NJ    | 08759 | 732.657.6100 | Dr. Joshua Shua-Haim<br>Ashley Clayton |
| A Phase 2, 26-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of PRX-03140 in Subjects with Alzheimer's Disease Receiving a Stable Dose of Donepezil  | Alzheimer's Research Corporation | Manchester | NJ    | 08759 | 732.657.6100 | Dr. Joshua Shua-Haim<br>Ashley Clayton |

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|---|--|-------------|-------|-------|--|---|
| A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of PRX-03140 as Monotherapy in Subjects with Alzheimer's Disease   | Alzheimer's Research Corporation                             | Manchester  | NJ    | 08759 | 732.657.6100                                       | Dr. Joshua Shua-Haim<br>Ashley Clayton              |
| Study AZ3110866, A Fixed Dose Study of SB-742457 versus Placebo when Added to Existing Donepezil Treatment in Subjects with Mild-to-Moderate Alzheimer's Disease  | Alzheimer's Research Corporation                             | Manchester  | NJ    | 08759 | 732.657.6100                                       | Dr. Joshua Shua-Haim<br>Ashley Clayton              |
| Double-Blind, Parallel-Group Comparison of 23mg Donepezil Sustained Release to 10mg Donepezil Immediate Release in Patients with Moderate to Severe Alzheimer's Disease   | Bio Behavioral Health  | Toms River  | NJ    | 08755 | 732.244.2299                                       | Ashtok Patel, M.D.                                  |
| A 12-week, Multicenter, Open Label Study to Evaluate the Effectiveness and Safety of Donepezil, Hydrochloride (E2020) in Subjects with Mild to Severe Alzheimer's Disease Residing in an Assisted Living Facility   | Bio Behavioral Health  | Toms River  | NJ    | 08755 | 732.244.2299                                       | Ashtok Patel, M.D.                                  |
| Receptor for Advanced Glycation Endproducts (RAGE) in Alzheimer's Disease   | Columbia University Medical Center                           | New York    | NY    | 10032 | 212.305.7661                                       | Ruth Tejada   |
| Pilot Trial of Metformin in Amnesic Mild Cognitive Impairment   | Columbia University Medical Center                           | New York    | NY    | 10032 | 212.305.4730<br>914.282.1710<br>jal94@columbia.edu | Dr. Luchsinger                                      |
| A Randomized, Double-Blind, Placebo-Controlled, Dose Ranging, Safety and Efficacy Study of Oral ELND005 (AZD-103) in Alzheimer's Disease  | Columbia University Medical Center                           | New York    | NY    | 10032 | 212.305.2077<br>lm2538@columbia.edu                | Lynda Mules   |
| Phase 3, Multicenter, Randomized, Double-Blind Placebo-Controlled, Parallel-Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN15727) in Patients with Mild to Moderate AD   | Columbia University Medical Center                           | New York    | NY    | 10032 | 212.305.2371                                       | Evelyn Dominguez                                    |
| Effect of gamma-Secretase Inhibition on the Progression of AD: LY450139 versus Placebo  | Columbia University Medical Center                           | New York    | NY    | 10032 | 212.305.2077<br>lm2538@columbia.edu                | Lynda Mules   |
| Aricept Plus a Behavioral Strategy to Improve Functional Tasks in Vascular Dementia: A Pilot Study  | Kessler Medical Rehabilitation Research and Education Center | West Orange | NJ    | 07052 | 973.324.3569<br>973.324.3564<br>973.324.3532       | Dr. Anna Barrett<br>Jenny Masmela<br>Yardena Mandel |
| A Phase 2, 26-week, Multicenter, Randomized, Double-Blind, Placebo Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of PRX-03140, in Subjects with Alzheimer's Disease Receiving a Stable Dose of Donepezil   | Memory Enhancement Center of America, Inc.                   | Eatontown   | NJ    | 07724 | 732.263.0101                                       | Dr. Joel Ross                                       |
| A Phase I, Multicenter, Randomized, Placebo-Controlled, Double-Blind Study to Assess the Safety, Pharmacokinetics, Pharmacodynamics, and Immunogenicity of Intravenous MABT5102A administered in a Single-Dose, Dose-Escalation Stage Followed by a Multidose, Parallel-Treatment Stage in Patients with Mild to Moderate Alzheimer's Disease | Memory Enhancement Center of America, Inc.                   | Eatontown   | NJ    | 07724 | 732.263.0101                                       | Dr. Joel Ross                                       |
| A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Efficacy and Safety Trial of Bapineuzumab (AAB-001, ELN15727) in Patients with Mild to Moderate Alzheimer's Disease who are Apolipoprotein E4 Carriers and E4 Non-Carriers  | Memory Enhancement Center of America, Inc.                   | Eatontown   | NJ    | 07724 | 732.263.0101                                       | Dr. Joel Ross                                       |
| A Randomized, Double-Blind, Placebo-Controlled Study Using a Bayesian Adaptive Design to Evaluate the Efficacy and Safety of ABT-089 in Subjects with Mild-Moderate Alzheimer's Disease on Stable Doses of Acetylcholinesterase Inhibitors  | Memory Enhancement Center of America, Inc.                   | Eatontown   | NJ    | 07724 | 732.263.0101                                       | Dr. Joel Ross                                       |

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| Study   | Location                                   | City                                | State | Zip   | Phone  | Contact                     |
|---|--|-------------------------------------|-------|-------|--|-----------------------------|
| Double-blind, parallel-group comparison of 23 mg Donepezil sustained release to 10 mg Donepezil immediate release in patients with moderate to severe Alzheimer's Disease   | Memory Enhancement Center of America, Inc. | Eatontown                           | NJ    | 07724 | 732-263-0101                                   | Dr. Joel Ross               |
| A randomized, double-blind, placebo-controlled, dose-ranging, safety and efficacy study of Oral ELND005 (AZD-103) in Alzheimer's Disease  | Memory Enhancement Center of America, Inc. | Eatontown                           | NJ    | 07724 | 732.263.0101                                   | Dr. Joel Ross               |
| A Double-Blind, Placebo Controlled, Randomized, Multi-Center Study Evaluating the Efficacy and Safety of Eighteen Months of Treatment with PF-04494700(TTP488) in Participants with Mild to Moderate Alzheimer's Disease  | Mount Sinai School of Medicine             | New York                            | NY    | 10029 | 212.659.8885                                   | Tessa Lundquist             |
| A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Safety, and Efficacy Study of Oral ELND005 (AZD-103) in Alzheimer's Disease   | Mount Sinai School of Medicine             | New York                            | NY    | 10029 | 212.241.5692                                   | Andrew Viagario             |
| A Trial of a Nutritional Supplement in Alzheimer's Disease  | Mount Sinai School of Medicine             | New York                            | NY    | 10029 | 212.241.8329                                   | Melissa Rushing             |
| The Development of NIC5-15 in the Treatment of Alzheimer's Disease  | Mount Sinai School of Medicine             | New York                            | NY    | 10029 | 212.241.8329                                   | Melissa Rushing             |
| A Home-Based Assessment (HBA) Study for Memory Protection Research  | Mount Sinai School of Medicine             | New York                            | NY    | 10029 | 212.241.8329                                   | Jessica Egan                |
| A Randomized, Double-Blind, Placebo-Controlled Study Using a Bayesian Adaptive Design to Evaluate the Efficacy and Safety of ABT-089 in Subjects with Mild-to-Moderate Alzheimer's Disease on Stable Doses of Acetylcholinesterase Inhibitors                     | Neurology Group of Bergen County, P.A.     | Ridgewood                           | NJ    | 07450 | 201.612.3089                                   | Jacqueline Warnock          |
| 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 Eε4 Carriers and Non-Carriers | Neuro Rehab Institute                      | Mount Arlington Hackettstown Newark | NJ    | 07856 | 908.879.6161                                   | Dr. Tramontano              |
| A Randomized, Double-Blind, Placebo-Controlled Study Using a Bayesian Adaptive Design to Evaluate the Efficacy and Safety of ABT-089 in Subjects with Mild-to-Moderate Alzheimer's Disease on Stable Doses of Acetylcholinesterase Inhibitors                     | Princeton Medical Institute                | Princeton                           | NJ    | 08540 | 609.921.3555x18<br>kfritz@gminstitutes.com     | Princeton Medical Institute |
| A Randomized, Double-Blinded, Placebo-Controlled, Dose Ranging, Safety, and Efficacy Study of Oral ELND005 (AZD-103) in Alzheimer's Disease   | Princeton Medical Institute                | Princeton                           | NJ    | 08540 | 609.921.3555x11<br>rsoika@gminstitutes.com     | Roberta Soika               |
| 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 to Moderate Alzheimer's Disease who are Apolipoprotein Eε4 Carriers      | Princeton Medical Institute                | Princeton                           | NJ    | 08540 | 609-921-3555x15<br>ptabachnik@gminstitutes.com | Polina Tabachnik            |
| 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 to Moderate Alzheimer's Disease who are Apolipoprotein Eε4 Non-Carriers  | Princeton Medical Institute                | Princeton                           | NJ    | 08540 | 609-921-3555x15<br>ptabachnik@gminstitutes.com | Polina Tabachnik            |
| An Open-label, Multiple-dose Study of the Safety and Tolerance of ST101 Tablets in Aricept-treated Alzheimer's Disease Subjects   | Princeton Medical Institute                | Princeton                           | NJ    | 08540 | 609-921-3555x15<br>ptabachnik@gminstitutes.com | Polina Tabachnik            |