BE PART OF THE CHANGE

Learn more about a unique opportunity for your loved one to take part in an Alzheimer's disease clinical trial today.

About Our Science

For decades, the direction of Alzheimer's research focused primarily on the management of amyloid plaques and tau tangles. Some progress has been made, and the road has been difficult; but what if there were new hope, and another path to pursue? Newer research in the past decade has led to over 4,000 research articles that link the problems in memory and judgement in Alzheimer's to the presence of inflammation and associated insulin resistance in the brain. Among these voices, researchers at the Mayo Clinic showed that over 80% of their Alzheimer's patients have, or are in the process of developing, Type II diabetes (i.e., insulin resistance). [1]

Inflammation initially arises as part of the body's process to protect and heal itself. When the underlying condition is enduring (as is the case in Alzheimer's), chronic inflammation may result and create a continuous cycle of disease. Insulin resistance interferes with the body's ability to process glucose, the essential energy source for cells. This could result in cell damage and death. When this happens in the brain, diminished memory and cognition may result. [2]

[1] Janson J, Laedtke T, Parisi JE, O'Brien P, Petersen RC, Butler PC. Increased risk of type 2 diabetes in Alzheimer disease. Diabetes. 2004 Feb;53(2):474-81. doi: 10.2337/diabetes.53.2.474. PMID: 14747300.

[2] Cunningham C, Hennessy E. Co-morbidity and systemic inflammation as drivers of cognitive decline: new experimental models adopting a broader paradigm in dementia research. Alzheimers Res Ther. 2015 Mar 24;7(1):33. doi: 10.1186/s13195-015-0117-2. PMID: 25802557; PMCID: PMC4369837.

About NE-3107

BioVie's drug candidate NE-3107 is a new molecule with a unique mechanism of action that is believed to have the potential to interrupt both inflammation and insulin resistance in the brain, which could provide a new approach to treating Alzheimer's disease. Although Alzheimer's is a complex condition, BioVie believes that inflammation in the brain plays a central role. Pre-clinical and clinical studies thus far show that NE-3107 has the potential to reduce inflammation throughout the body, including the brain. By reducing inflammation, NE-3107 may allow brain cells to function better and survive longer. Inflammation interferes with the brain's ability to use energy needed for healthy memory. Because NE-3107 may enhance energy transfer (i.e., improving insulin sensitivity) within the brain, BioVie believes that NE-3107 has the potential to improve memory. In short, the dual effects of reducing inflammation and reducing insulin resistance have the potential together to improve nerve cell function and survival.

About The Trial

BioVie is currently conducting a late-stage clinical trial whereby the first fully qualifying 320 patients with mild to moderate Alzheimer's Disease may participate. Study participants will receive extensive medical testing and treatments. Participants will have about a 50% (1 in 2) chance of receiving NE-3107 and about a 50% (1 in 2) chance of receiving placebo (an inactive capsule that looks like the NE-3107). The study is double-blind meaning that neither you nor the Study Doctor will know who is receiving NE-3107 or placebo. Study participants may be among the first people to have the chance to receive NE-3107, with its unique dual mechanism of action, while contributing to the advancement of medical understanding in treating Alzheimer's.

Potential Side Effects

In completed clinical studies of NE-3107, when NE-3107 was compared to placebo, the most commonly observed event has been headache (11%) versus placebo (10%). Other possible side effects may include increases in blood glucose levels or cholesterol levels, and decreases in blood calcium levels or blood sodium levels. This is not a full listing of all possible observed events. For a full list of side effects, talk with your physician or reference the informed consent. There also may be unknown or unexpected adverse effects or side effects from the drug.

Who Qualifies to Participate

- People who are from 60 to 85 years of age at the beginning of their study participation
- Show medical evidence of mild to moderate Alzheimer's Disease, for instance:
  - May be getting lost in familiar places
  - May become confused while performing previously routine tasks such as bill paying or cooking
  - New or worsening challenges with language, writing, math, drawing or copying pictures, or in following multi-step directions
  - Decision making may be difficult, or errors in decision making are new or becoming noticeable
  - Others may notice words, phrases, or questions are repeated, or the frequency or intensity of repeating has increased
- Generally healthy enough to participate in all study activities and travel
- Have shown an important decline in memory and daily function from a previous higher level of ability
- Cause of memory loss is not due to stroke, cardiovascular, or other non-Alzheimer's causes
- No episodes of violence or aggression
- Not taking insulin
- Has never been diagnosed with breast cancer

Benefits of Participation

- All study treatments and tests at no cost
- Complete physical examinations and comprehensive laboratory evaluations
- Detailed evaluations of cognitive function, memory, and recall
- Choice to participate in two types of before and after brain imaging tests:
  - Volumetric magnetic resonance imaging (looking at structure and size of brain locations devoted to memory)
  - Brain energy testing (looking at how the brain utilizes glucose in a positron emission tomography scan)
- There will be 11 trips to the study doctor over a period of about 7 months
- Study participants and their study partner/caregiver may also receive reimbursement for time spent traveling to the clinic and visits with the doctor

Be a part of a unique opportunity to help advance Alzheimer's research and be a part of the change for future generations.

Find out how to get involved today.

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