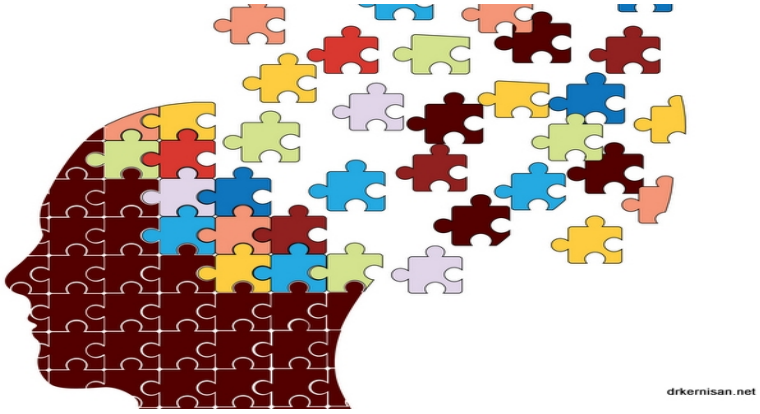
Study phase and description:

A Placebo-Controlled, Double-Blind, Parallel-Group, 18-Month Study With an Open-Label Extension Phase to Confirm Safety and Efficacy of BAN2401 in Subjects with Early Alzheimer's Disease

Study name: Clarity AD

Study population: Individuals living with Early Alzheimers Disease.



Header:

Are you having problems with your memory and thinking abilities or concerned about recent changes? Do you have a family history of Alzheimer's disease (AD)? Have you recently received a diagnosis of AD?

Consider participating in the Clarity AD clinical trial. This study will assess the safety, tolerability, and effectiveness of a new investigational medication to determine if it will stop or reduce the amount of amyloid in the brain (a protein that can build up in the brain of individuals with AD) and evaluate if it will stop or slow the progression of symptoms in individuals living with early Alzheimer's disease.

Time frame:

This study will last for approximately 2 years. After the completion of the double-blind portion of the study drug period, you may receive an invitation to participate in the optional open-label extension study phase, which lasts for another 18 months.

May be eligible:
Male/Female, Age: ages 50-90 years of age

May be offered:

- $50.00 dollars each visit for study participant
- Parking at no cost

May Be Required:
Office visits, physical exam, ECG, blood draws, urine tests, memory and thinking tests, IV medication infusion, MRI scans, PET scans, or optional lumbar punctures (spinal tap)

Overview:

What are we studying:

Are you having memory and thinking problems? Have you recently been diagnosed with Alzheimer's disease (AD)?

Are you interested in participating in a clinical trial to help scientist understand if a new medication called BAN2401 can slow the progression of amyloid buildup in the brain?

This study is assessing the safety, tolerability and effectiveness of BAN2401 a monoclonal antibody (passive vaccine). This investigational new medication is being evaluated to understand if it can stop or reduce the buildup of amyloid in the brain and potentially stop or slow the progression of symptoms of disease progression in individuals living with AD.

What is the study treatment?

A new investigational medication (BAN2401, a monoclonal antibody-passive vaccine). BAN2401may halt or reduce the buildup of amyloid (a protein) in the brain. This protein buildup can lead to impairment in memory or thinking.

BAN2401 is a monoclonal antibody, antibodies are proteins produced by the immune system that bind to foreign substances in the body called antigens. BAN2401 binds to amyloid in the brain in patients with AD and has been shown to reduce the buildup of this protein.

In this study, you will get either BAN2401 or placebo. A placebo looks like a drug but has no active ingredient. BAN2401 is an experimental drug, which means health authorities such as the Food and Drug Administration (FDA) have not approved it for the treatment for AD or other conditions. BAN2401 is in early development and has been previously studied in healthy subjects and people with AD.

Who is the Sponsor of the Study?

The sponsor of this study is Eisai pharmaceutical company.

Why is this important?

There are currently no approved disease modifying agents for individuals living with AD so it is important to find a treatment that could prevent further brain changes. Please consider enrolling in this study?

How many people will enroll in this study?

Approximately 1,566 subjects will take part in this study in about 200 research centers in the United States of America, Canada, Europe, Asia, and Japan.

Number visits:

This trial will last approximately 2 years and during that period there will be approximately 45 study visits. There may be more visits initially to monitor your safety on the study drug.

Study procedures:
Office visits, physical exam, ECG, blood draws, urine tests, memory and thinking tests, IV medication infusion, MRI scans, PET scans, or optional lumbar punctures (spinal tap)

Who may be eligible?

You may be eligible for the Clarity Trial if you:

- You have recently been diagnosed with Mild Cognitive Impairment or early Alzheimer's Disease
- Have problems with your memory and thinking abilities
- Are between the ages of 50 - 90
- Have a study partner who knows you well and can attend periodic visits with you and tell us about your health, memory, and well-being

What you may be asked to do:

- Office visits
- Physical exam
- Urine tests
- Blood draws
- Memory and thinking tests
- MRI scans
- PET scans
- ECG
- IV infusion
- Optional lumbar puncture (spinal tap)

What you may get for participating:

- On-site parking at no cost to you

- Financial compensation for each visit ($50.00) for you and your study partner

Where will the study visits take place?
Location
Center for Alzheimer Research and Treatment
Brigham and Women's Hospital
60 Fenwood Road, 1st floor

Most of the visits for this trial will be conducted at the Center for Alzheimer Research and Treatment (CART) at Brigham& Women's Hospital, but a few visits (the PET scans) will be conducted at Massachusetts General Hospital.

Who should I contact?
If you are interested and would like more information, please contact:

Allyson Pulsoni: Phone- (617) 525-9554 apulsoni@bwh.harvard.edu
Or The Center for Alzheimer Research and Treatment main line: (t) **617-732-8085**

Principal Investigator
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