What is Early Alzheimer's Disease?

Alzheimer's is a brain disease caused by a buildup of sticky clumps called amyloid plaques and tau tangles. In people with Alzheimer's disease, these changes damage the brain and eventually lead to dementia.

The most common early symptoms of Alzheimer's disease include memory loss, new problems speaking or writing, difficulty learning or solving problems, and changes in mood and personality.

Early Alzheimer's disease includes patients with:

- Mild cognitive impairment (MCI) due to Alzheimer's disease – This is when people have more memory or thinking problems than other people their age but can still live normally.
- Mild dementia due to Alzheimer's disease – This is when peoples' memory or thinking problems may become noticeable and start to affect their daily life.

Alzheimer's disease is progressive, which means it gets worse over time.

What is a clinical trial?

Clinical trials are research studies that help doctors find out if investigational drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions. Clinical trials are carefully controlled research studies that are done to get a closer look at investigational drugs and procedures.

The safety of the people who volunteer to be in clinical trials is the highest priority.

There are rules in place to:

- Help protect the rights, safety, and well-being of clinical trial participants
- Make sure trials follow strict scientific and ethical guidelines

Before a clinical trial can begin, an Institutional Review Board (IRB) or Ethics Committee (EC) must review the clinical trial to make sure it follows regulations and ethical guidelines.

Notes:

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Learn about a clinical trial for

Early Alzheimer's Disease

Information for adults 50-85 years of age who have mild cognitive impairment or mild dementia due to **Alzheimer's disease**.

Find out if you may be eligible to participate.

About this clinical trial

Researchers want to learn about an investigational drug called MK-2214 in people with mild cognitive impairment or mild dementia due to Alzheimer's disease.

The goals of this trial are:

- Test the safety of MK-2214
- See how well MK-2214 may work to slow the progression of Alzheimer's disease

MK-2214 is experimental. It has not been approved to treat or prevent mild cognitive impairment or mild dementia due to Alzheimer's disease or other conditions.

Who can join this clinical trial?

There are eligibility criteria that will determine if you qualify to participate. You may be able to join this clinical trial if you:

- Are 50-85 years of age
- Have mild cognitive impairment or mild dementia due to Alzheimer's disease
- Have a person (trial partner) who can go with you to specific trial visits and:
  - Knows you well
  - Is in regular contact with you
  - Can answer questions about you

Participants are allowed to continue taking certain medicines for Alzheimer's disease (including, but not limited to, brexpiprazole, donepezil, rivastigmine, galantamine, and memantine) as long as the dose has not changed for at least 3 months.

The trial doctor will talk with you about other requirements to join this trial and possible benefits, risks, and side effects.

What trial drug will I get?

If you qualify and decide to join, you will be randomly (by chance) assigned by a computer to get either the investigational drug, MK-2214, or the placebo. A placebo looks like the investigational drug but has no active ingredients. Using a placebo helps researchers better understand the actual effects of an investigational drug.

You will have a 3-in-5 chance of getting the investigational drug, MK-2214, and a 2-in-5 chance of getting the placebo.

You will get your assigned trial drug through a needle in a vein. This is called intravenous (IV) infusion. You will get IV infusions of your assigned trial drug every 4 weeks for about 2 years.

You, the trial doctor and team, and your trial partner will not know whether you are getting the investigational drug or the placebo. In case of a health emergency, they can find out.

What will happen during this clinical trial?

If you qualify and decide to take part, you and your trial partner will be in this trial for about 2.5 years and visit the trial site about once a month.

During your trial visits, you may get:

- Your assigned trial drug
- Physical exams
- Blood and urine tests
- Electrocardiograms (ECG; a test that shows how well your heart is working)
- Imaging scans, such as MRI and PET scans (scans that help the doctor see your brain)
- Asked questions or to do tasks that measure how well you think, reason, remember, and make judgments; your trial partner will also answer questions at specific visits.

The trial doctor will talk with you more about what may happen at trial visits. You can ask them any questions you have about what happens during trial visits and how often they will happen.

Deciding to join a clinical trial is something only you, those close to you, and your care team can decide together. If there is anything you do not understand, ask the trial doctor.

If you qualify and decide to participate

- You will get the investigational drug or placebo and all trial-related medical tests at no cost to you.
- You will be closely monitored by a trial doctor.
- You may be eligible to be reimbursed for trial-related travel expenses.
- Joining the trial is voluntary, and you can leave the trial at any time and for any reason.

To learn more about this clinical trial, including risks and possible benefits of joining, please contact: