# Clinical research study for people with symptoms of the early stages of Alzheimer's disease

## TRAILRUNNER-**ALZ 2**

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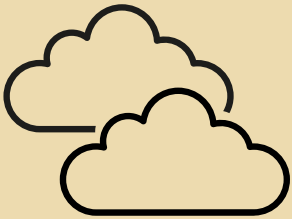
**Have you noticed changes in your memory or ability to think clearly?**

# Are you worried that your memory loss is more than just normal forgetfulness?

**If you have noticed changes in your memory and thinking, you may wonder what to do next.**

**This brochure will explain the purpose of clinical research studies. It will help you decide if the TRAILRUNNER-ALZ 2 study might be right for you.**

**We hope this information will help you understand your options and take action.**



**Early symptoms of Alzheimer's disease include a small but clear decline in memory, thinking, language and judgment skills**

## Searching for a way to treat Alzheimer's disease

Doctors and researchers are trying to find medicines that can treat people with the early stages of Alzheimer's disease. Clinical research studies like the **TRAILRUNNER-ALZ 2** study are an important part of this work.

## What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about investigational medicines, such as:

- Is it safe?
- Does it work?
- Are there side effects?

All medicines must be tested in clinical research studies before they can be approved for doctors to give to patients. Without people taking part in these studies, we would not have new medicines.

**Investigational medicine** means it is still being tested in clinical research studies. It has not yet been approved for doctors to give to patients.

A **placebo** looks the same as the investigational medicine but does not have any real medicine in it.

# About the TRAILRUNNER-ALZ 2 study

Amyloid is a protein that your body makes naturally. In some people, amyloid proteins build up in the brain and form what we call plaques.

Tau is another protein that your body makes naturally. It plays an important role in a healthy brain. In patients with Alzheimer's disease, a type of tau is made that is not good for the brain. This type of tau sticks together, and forms what we call tau tangles.

Amyloid plaques and tau tangles are both found in people with Alzheimer's disease. Amyloid plaques form before tau tangles but both lead to problems with memory and thinking.

Researchers think that removing these amyloid plaques might slow down or delay those problems with memory and thinking.

The **TRAILRUNNER-ALZ 2** study will see if an investigational medicine can help treat people with the early stages of Alzheimer's disease. The investigational medicine being tested in this study may remove amyloid plaques.

The study will have about 1300 participants.

## What does the TRAILRUNNER-ALZ 2 study involve?

The study will last up to about 3 years, and you may have up to 23 study visits.

Your study partner should come to some study visits with you. If they cannot come to a visit, they should be available by phone for any questions or follow-up. They must be able to tell the research team about any changes in your memory and thinking.

A **study partner** is a person who knows you well and would notice any changes in your memory, thinking, mood and behavior. This could be your spouse, partner, friend, family member or someone whose job it is to help you.

People taking part in the study will get the study medicine (investigational medicine or placebo) as an injection into their skin using a syringe.

For the weekly at home injections, either you will self-inject the study medicine, or your study partner will give you the injection. You will do this after you get training at the site, and you are both comfortable.

The study has up to 5 parts, including an extension to the study treatment period. You will get the investigational medicine either during the study treatment period or during the study treatment extension period.

## Screening period:
## Up to 13 weeks, 2 planned visits

- To check if the study is right for you
  - You may or may not qualify to take part in this study
- Screening activities will take more than 1 day to finish

## Study treatment period
## About 1 year and 6 months, up to 11 planned visits

- You will get the study medicine 36 times during this period. The injections will be 1 week apart

## Intermediary period
## 2 weeks

- This is the 2 weeks between the end of the study treatment period and start of the study treatment extension period

## Study treatment extension period
## About 1 year, up to 9 planned visits

- You will get the study medicine 36 times during this period. The injections will be 1 week apart

## Follow-up period
## Up to 12 weeks, 1 visit if needed

- Final study health checks
- Your study doctor will let you know if you need to come back for a follow-up visit

## Why should I think about joining this study?

A medicine might work differently depending on other diseases a person might have, and sometimes on their race, gender and ethnicity. It is important to test an investigational medicine in all people it is meant to help. This means we need a diverse group of people taking part in the clinical research study.

### What are the possible benefits of taking part?

The benefits of taking part in the TRAILRUNNER-ALZ 2 study are:

- Getting actively involved in healthcare research for Alzheimer's disease
- Helping others by advancing medical research

If you choose to take part, you will get at no cost to you:

- All study-related medicines
- All study-related care and check-ins
- Access to specialized doctors or researchers in Alzheimer's disease

**You do not need to have health insurance to take part.**

## Can I join this study?

**Yes,** you may be able to join the **TRAILRUNNER-ALZ 2** study if you:

- Are aged 60 to 85 years old
- Have memory loss that has gotten worse over time
- Have a trusted study partner

Your study partner will need to:

- Consent to the research study
- Go to study visits and complete questionnaires
- Give injections (if you need help with this)

**This study is from Eli Lilly and Company**

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