

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

## TRAILBLAZER-ALZ 6

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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?

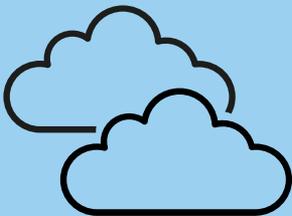


If you have noticed changes in your memory and thinking, you may wonder what to do next.

**This brochure will:**

- explain the purpose of clinical research studies
- help you decide if the **TRAILBLAZER-ALZ 6** 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 safely treat people with the early stages of Alzheimer's disease. Clinical research studies like the **TRAILBLAZER-ALZ 6** 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 like the investigational medicine but does not have any real medicine in it.

## About the **TRAILBLAZER-ALZ 6** 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. This may 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 **TRAILBLAZER-ALZ 6** study will see if different doses of the investigational medicine are safe and effective for 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 800 participants.

## What does the TRAILBLAZER-ALZ 6 study involve?



The study will last up to about 1 year and 9 months.

Your study partner must go with you to sign consent. At study visits we need to collect information about side effects and other medicines you are taking. If your study partner cannot go to these visits with you, they will need to be available by telephone. 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 investigational medicine as an infusion, which slowly drips the medicine through a tiny tube directly into your vein.

There will be 4 groups. Each group will get a different dose of the investigational medicine. You may get the investigational medicine at some visits and the placebo at other visits.

The study has up to 3 parts.



## Screening period:

### Up to 7 weeks, 1 planned visit

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



## Study treatment period:

### About 1 year and 6 months, up to 24 planned visits

- You will get the study medicine during this period.
- The study doctor may ask you to stop the study medicine early. If this happens you still need to attend the study visits.
  - If you have stopped taking the study medicine, you may be able to attend some of the visits by phone.



## Follow-up period:

### 12 weeks after study treatment period, 1 visit

- Final study health checks

## 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, sex 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 **TRAILBLAZER-ALZ 6** 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 **TRAILBLAZER-ALZ 6** 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

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

