A clinical research study for people who may have early Alzheimer's disease or may be at risk for developing symptoms of Alzheimer's disease



TRAILRUNNER-ALZ 3













Have you noticed changes in your memory or thinking, or are you concerned you may be at risk of Alzheimer's disease?

If so, you may be able to take part in a clinical research study for people with early Alzheimer's disease.

Searching for ways to help people with early Alzheimer's disease

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Doctors and researchers are trying to find medicines that can help people with early Alzheimer's disease. Clinical research studies like the **TRAILRUNNER-ALZ 3** study are an important part of this work.

This brochure will:

- explain the purpose of clinical research studies
- help you decide if the TRAILRUNNER-ALZ 3 study might be right for you

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

If you have early Alzheimer's disease or are at risk for developing symptoms of Alzheimer's disease, the TRAILRUNNER-ALZ 3 study may be for you.

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?
- Does it cause 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.

The medicine that participants take in a clinical research study is called the study medicine. Different clinical research studies might have different types of study medicines. In the **TRAILRUNNER-ALZ 3** study, the study medicine can be investigational medicine or placebo.

Investigational medicine means it is still being tested in clinical research studies.

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

About the TRAILRUNNER-ALZ 3 study

The **TRAILRUNNER-ALZ 3** study will see if an investigational medicine can help treat people with early Alzheimer's disease.

Amyloid is a protein that your body makes naturally. Researchers think the symptoms of Alzheimer's disease could be caused by a build-up of amyloid proteins in the brain. These amyloid proteins can stick together and form tiny clumps known as amyloid plaques. Amyloid plaques may lead to problems with memory and thinking.

The investigational medicine being tested in this study may remove amyloid plaques and could delay the time it takes before problems with memory and thinking start or get worse.

Participants need to have a reliable study partner to join this study.



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

What does the TRAILRUNNER-ALZ 3 study involve?

If you qualify to take part in the **TRAILRUNNER-ALZ 3** study, you will be randomly (that is by chance) assigned to either the investigational medicine group or the placebo group. For every 2 study participants, 1 will get investigational medicine and 1 will get placebo.

You will get an injection under the skin using a prefilled syringe. The first 5 doses will be at the clinic. The study team will give you these injections and show you how to do this. You or your study partner can give you the remaining injections at a convenient location, like at home or you can go to the clinic. If your study partner is helping you, the study team will also show them how to give the injections.

This study will last about 5 years. It has 5 parts, including an optional extension to the study treatment period for eligible participants. After the observation period, if the investigational medicine is safe and effective, participants who received placebo may take part in the extension period and get investigational medicine. The study team will explain this to you in more detail.

What does the TRAILRUNNER-ALZ 3 study involve? (continued)

During the study you will attend visits with doctors and researchers in-person at a clinic.

Your study partner should come to 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.



Participants and their study partners may need to use electronic tablets to complete study-related questionnaires and video calls. The study team may use the tablets to collect participants' and their study partners' voice and video recordings for some questionnaires.

The TRAILRUNNER-ALZ 3 study has 5 main study periods



Pre-screening and Screening period

About 5 months, 2 planned visits

To check if the study is right for you



Study treatment period

About 1 year and 6 months, about 9 visits

- You will get the study medicine this will either be the investigational medicine or the placebo
- You will be given the first 5 doses at the clinic once every 2 months for the first 8 months
- The remaining 10 doses can be at the clinic or at home - these will be once every month
- You, your study partner, and your study team will not know which study medicine you are taking

The TRAILRUNNER-ALZ 3 study has 5 main study periods (continued)



Observation period

About 2 to 3 years - this period may be extended About 5 to 7 clinic visits - additional visits may be added as needed (around every 6 months) until the end of the study

- You will get study health checks during this time
- If you received all 15 doses in the study treatment period, you will not get the investigational medicine or the placebo during this period. However, it is important to go to your study visits to monitor for any changes in your memory and thinking



Optional extension study treatment period

About 1 year and 6 months, about 10 visits

- Eligible participants from the placebo group may opt to enter this period
- If selected, you will get the investigational medicine
- You will be given the first 5 doses at the clinic once every 2 months for the first 8 months
- The remaining 10 doses can be at the clinic or at home - these will be once every month
- You, your study partner, and the study team will know that you are taking the investigational medicine

The TRAILRUNNER-ALZ 3 study has 5 main study periods



Follow-up period

5 months after getting the last injection, 1 planned visit

At the time you complete or discontinue the study, if more than 5 months have passed since your last dose, this visit is not required.

• Final study health and safety checks

Some of the clinic visit activities may take more than 1 day to finish.

Why should I think about joining this study?

A medicine might work differently depending on other health conditions a person might have, and sometimes on their genes, sex, race, 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 3** study are:

- getting actively involved in healthcare research for people with 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, and
- access to specialized doctors and researchers in Alzheimer's disease.

You do not need to have health insurance to take part in the TRAILRUNNER-ALZ 3 study.

Notes

Can I take part in this study?

Yes, you may be able to take part in this study if you:

- Are aged 55 to 80 years old
- Have no to mild issues with your memory
- Are willing to obtain a blood test as part of the study that checks whether you have an abnormal protein associated with Alzheimer's disease, and
- Have a reliable study partner.

Your study partner will need to:

- Consent to the research study
- Go to study visits and complete questionnaires using electronic tablets or video calls
- Give injections (if you need help with this)

Can I change my mind about taking part?

Taking part in the **TRAILRUNNER-ALZ 3** study is your choice. If you decide to take part, you may leave the study at any time for any reason.

This is a study from Eli Lilly and Company.

For more information please:

Scan the QR code or visit https://e.lilly/4dbUoMr



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