



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

Participant visit guide



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TRAILBLAZER-ALZ 6 clinical research study

Lilly





Welcome!

.....
Thank you for joining the TRAILBLAZER-ALZ 6 study

This guide will tell you more about what will happen at your study visits and what you will need to do. Of course, if you have any questions, you can talk to the **TRAILBLAZER-ALZ 6** study team. They are there to help!

Contact Details:



What is the aim of the TRAILBLAZER-ALZ 6 study?

.....

The **TRAILBLAZER-ALZ 6** study will see how different doses of an investigational medicine (a medicine being studied) compare in their safety and effectiveness in treating people with early stages of Alzheimer’s disease.

The study involves people who have memory loss that has gotten worse over time.

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Study overview

This study has up to 3 parts.



Screening period

(up to 7 weeks, 1 planned visit)

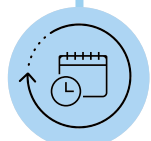
- » To check if the study is right for you
 - You may or may not qualify to take part in this study
- » Screening activities will take more than 1 day to finish
- » You may have finished this part already



Study treatment period

(about 1 year and 6 months, up to 24 planned visits)

- » You will get the study medicine during the study treatment 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

(up to 12 weeks, 1 visit)

- » Final study health checks

In total, you will be part of this study for up to 1 year and 9 months.

Study medicine overview

Study medicine can be either the investigational medicine or the placebo.

You will get the investigational medicine during this study.

There are 4 treatment groups. All treatment groups will get the investigational medicine.

You may get the investigational medicine at some visits and the placebo at other visits. Neither you nor the study doctor will know when you are getting the investigational medicine and when you are getting placebo.

What is an investigational medicine?

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

What is a placebo?

A placebo looks like the investigational medicine but does not have any real medicine in it.



Sometimes, people may feel better or worse because of what they expect or believe treatment will do. If at any time you feel unwell or your condition changes, please call the study team.

It is important to make sure that everybody gets the same number of infusions in this clinical research study. You may get investigational medicine at some visits and placebo at other visits. This helps to make sure that the study results are not influenced by what people expect.



How will I get the study medicine?

All participants will get the study medicine as an infusion.

Study treatment period

You will be randomly assigned (that is, by chance) to 1 of 4 treatment groups.

All treatment groups will get the investigational medicine.

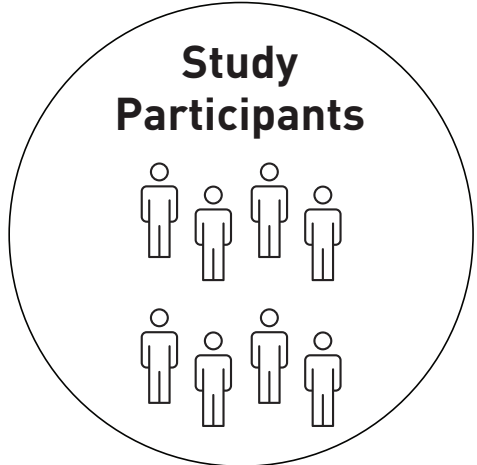
Each treatment group will get a different dose of investigational medicine.

There is a picture on the next page showing how participants are grouped.

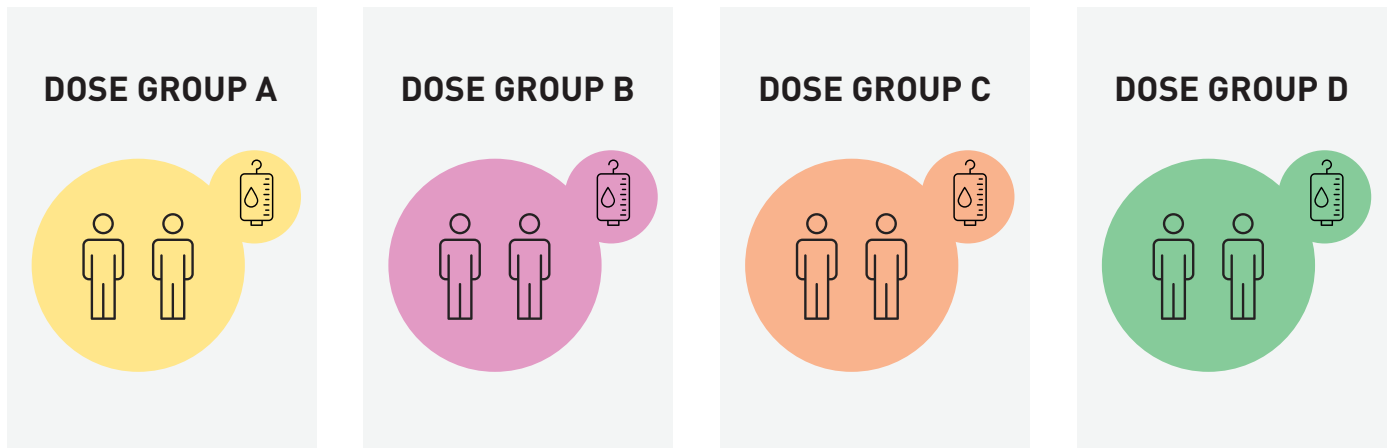


The infusion will drip the medicine through a tiny tube directly into your vein, over at least 30 minutes.

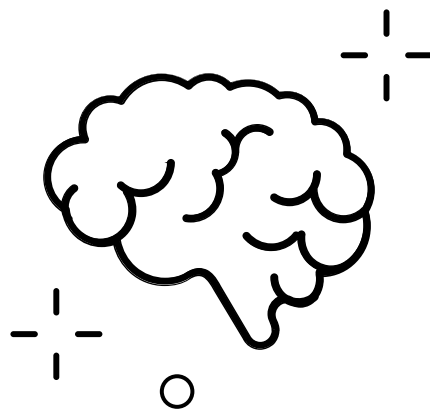




Randomisation



Each treatment group will get a different dose of investigational medicine



How does the investigational medicine work?

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.

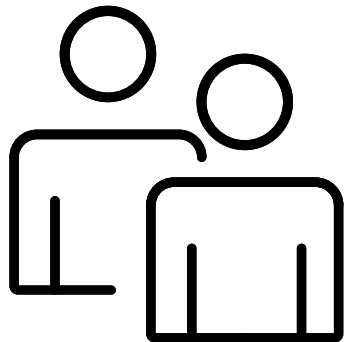
The investigational medicine being tested in this study removes amyloid plaques in the brain.

Stopping the study medicine early

At screening and some study treatment visits, your study doctor will measure amyloid plaques in your brain (using a PET scan). If these amyloid plaques drop below a certain level, your 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.





Information for study partners

You are being asked to take part in this research study because you are the family member, friend, or someone whose job it is to help the study participant. Study partners play a key role in this research study.

As a study partner, you will need to:

- » Sign a consent form
- » Go with the participant to study visits or be available by telephone
- » Take calls from the research team and seek their guidance between visits as needed

Study partners must go with the participant to sign consent.

At study visits we will need to collect information about side effects, and other medicines the participant is taking. If you cannot go to these visits with the participant, you will need to be available by telephone.

If you change your mind about taking part, you can leave the study at any time. However, the study participant cannot be in this study without a study partner. If you are not able or not willing to take part, please talk with your study team for guidance.





Your study centre visits

The next few pages will tell you what to expect at each study visit. Please ask the study team if you have any questions.

Visit checklist

When going to your visits please:

- bring a list of any other medicines you have taken
- bring your study partner
 - if your study partner cannot come, they will need to be available by telephone
- be ready to talk about any symptoms, side-effects, or questions you may have

Note: It is important that you go to all your study visits. If you need to reschedule a visit, please call your study doctor as soon as possible.



If at any time you feel unwell or your condition changes, please call the study team.





What can you expect at study visits?



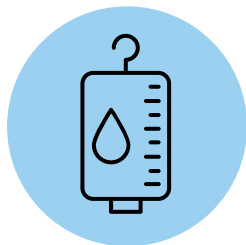
The study doctor will do some health checks at your study visits. These checks may be done at one, some or all of your visits. Some of these checks are described here.



Informed consent

Your study doctor will explain the study to you and your study partner. They will make sure you understand the study and what is needed from you and your study partner. They will also answer any questions you have.

Once you and your study partner understand the study and are happy to take part, you will both sign the consent form. You are now taking part in the study.



Get study medicine

You will get the study medicine, as an infusion, at the site.





Questions

During screening a study team member will ask you questions about your age, sex, and race.

They will also ask:

- » how much alcohol or caffeine you drink
- » if you smoke
- » if you use nicotine replacement

At each visit a study team member will ask you questions about:

- » your health and how you are feeling
- » any medicines you have taken or are taking
- » any healthcare visits you have had, including any hospital stays or surgeries



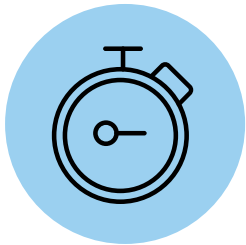
Physical examination

The study doctor will check your general appearance, skin, head, neck, glands, stomach, and back. At most visits, the study doctor will focus on the parts of your body where you have symptoms. Your height will be measured once at the start of this study. Your weight will also be measured at several visits during the study.



Neurological examination

A study team member will check your balance and how you walk. They will also ask you to do tasks to make sure your nerves are working the right way.



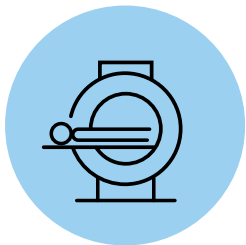
Vital signs

A study team member will measure your blood pressure, heart rate, and temperature.



Cognitive testing

During screening, a study team member will ask you questions. These questions will be used to check your memory, thinking, understanding and communication.



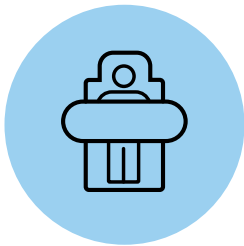
Magnetic Resonance Imaging (MRI) testing

At some visits, an MRI of your brain will be performed. Each MRI checks for signs of changes in the brain.



Electrocardiograms (ECGs)

During screening you will get a test that measures the electrical activity of your heartbeat. Your study doctor will let you know if you need to have more ECGs.



Positron Emission Tomography (PET) scan

PET scans will be used at some visits to take images of your brain. These images will help check the amount of amyloid plaque in your brain.



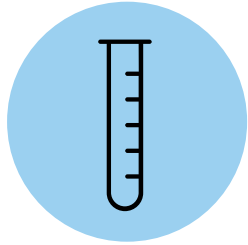
Safety assessment

At some visits, your study doctor will ask questions to check on your mental health and safety. This may include questions about side effects from medicines you are taking.



Urine sample

During screening you will provide a urine sample. The study team will test your urine sample to check your general health.



Blood tests

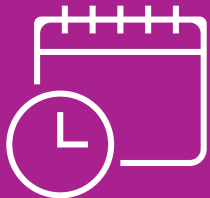
You will need to give some samples of your blood, which will be used to check your general health. Some blood samples will also be used to check:

- » How much of the investigational medicine is in your blood
- » If your body is making antibodies against the investigational medicine
- » For biomarkers
- » Your genes

Antibodies are proteins that are made by your body's defence system.

A **biomarker** is a substance in the body that can be used to help diagnose a disease and/or measure the stage of a disease. It can also be used to check if a medicine is working.

Genes are passed on to you from your parents. They carry the information that decides how you look and how your body works. These samples will help us understand how the medicine works in different people and which genes affect the disease.



Visit by Visit Guide



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Screening period (may take more than 1 day to finish)

Visit 1: Screening visit (up to 7 weeks before study treatment period)

Date: _____ Time: _____



Informed consent
(you and your study partner)



Neurological examination



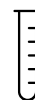
Check if the study is right for you



ECG



Questions



Blood tests



Cognitive testing



Urine sample



Safety assessment



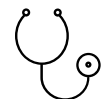
MRI



Vital signs



PET scan



Physical examination



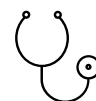
Study treatment period

Visit 2 at week 0

Date: _____ Time: _____



Check if the study is still right for you



Physical examination



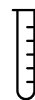
Questions



Neurological examination



Safety assessment



Blood tests



Vital signs



Get study medicine



Notes

Handwriting lines for notes.





Visit 3 at week 2

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 4 at week 4

Date: _____ Time: _____



Questions



Blood tests



Safety assessment



MRI



Vital signs



Get study medicine



Notes





Visit 5 at week 6

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 6 at week 8

Date: _____ Time: _____



Questions



Blood tests



Safety assessment



Get study medicine



Vital signs



Notes





Visit 7 at week 10

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 8 at week 12

Date: _____ Time: _____



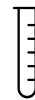
Questions



Neurological examination



Safety assessment



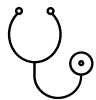
Blood tests



Vital signs



MRI



Physical examination



Get study medicine



Notes

Handwriting lines for notes.





Visit 9 at week 14

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 10 at week 16

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes

Multiple horizontal lines for writing notes.



Visit 11 at week 20

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes



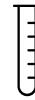


Visit 12 at week 24

Date: _____ Time: _____



Questions



Blood tests



Safety assessment



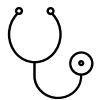
MRI



Vital signs



PET scan



Physical examination



Get study medicine



Neurological examination



Notes

Four horizontal lines for writing notes.





Visit 13 at week 28

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 14 at week 32

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 15 at week 36

Date: _____

Time: _____



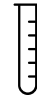
Questions



Neurological examination



Safety assessment



Blood tests



Vital signs



Get study medicine



Physical examination



Notes





Visit 16 at week 40

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 17 at week 44

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 18 at week 48

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes



Visit 19 at week 52

Date: _____

Time: _____



Questions



Blood tests



Safety assessment



MRI



Vital signs



PET scan



Physical examination



Get study medicine



Neurological examination



Notes



Visit 20 at week 56

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes

Multiple horizontal lines for taking notes.



Visit 21 at week 60

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 22 at week 64

Date: _____ Time: _____



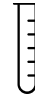
Questions



Neurological examination



Safety assessment



Blood tests



Vital signs



Get study medicine



Physical examination



Notes

Handwriting lines for notes.





Visit 23 at week 68

Date: _____

Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 24 at week 72

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes





Visit 25 at week 76

Date: _____

Time: _____



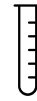
Questions



Neurological examination



Safety assessment



Blood tests



Vital signs



PET scan



Physical examination



Notes





Early discontinuation visit

If you decide to leave the study early, you will have this visit.

Date: _____ Time: _____



Questions



Neurological examination



Safety assessment



Blood tests



Vital signs



MRI



Physical examination



PET scan



Notes

Five horizontal lines for taking notes.





Follow-up period

You might need to attend a follow-up visit 12 or more weeks after you last got the study medicine

Date: _____ Time: _____



Questions



Vital signs



Safety assessment



Get study medicine



Notes







Thank you for being part of the **TRAILBLAZER-ALZ 6** study. We are very grateful that you and your study partner give your valued time to take part in this important clinical research study.

Your wellbeing and safety are our biggest concern. You will have support from a team of doctors, nurses, and other researchers throughout the research study. Please call them at any time during the study if you have questions.

By working together in this study, we can learn more about making progress in treating early Alzheimer's disease.

TRAILBLAZER-ALZ 6

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