

Alzheimer's Disease (AD)

A study to compare how well trontinemab works against a placebo in people with early symptoms of Alzheimer's disease

A Study of Trontinemab in Participants With Early Symptomatic Alzheimer's Disease

Trial Status
Recruiting

Trial Runs In
11 Countries

Trial Identifier
NCT07169578 2024-518006-40-00
WN45443

The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

Trial Summary:

The purpose of this study is to assess the efficacy and safety of trontinemab in participants with early symptomatic Alzheimer's disease (AD) (mild cognitive impairment [MCI] to mild dementia due to AD).

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT07169578 2024-518006-40-00 WN45443
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
>=50 Years & <= 90 Years

Healthy Volunteers
No

1. Why is this study needed?

Alzheimer's disease (AD) is a type of dementia that affects memory, thinking and behaviour. Symptoms usually develop slowly and get worse over time, becoming severe enough to interfere with daily tasks. It is believed that changes in two proteins in the brain, beta-amyloid and tau, cause AD. Plaques (clumps of beta-amyloid) and tangles (twisted threads of tau) are the main reasons that brain cells are damaged. These two proteins are the focus of many researchers working on treatments that could help slow down or stop AD.

This study is testing a medicine called trontinemab. It is designed to remove amyloid plaques from the brain and is being developed to treat early symptoms of AD.

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Trontinemab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved trontinemab for the treatment of AD.

This study aims to compare how effective and safe trontinemab is against a non-active medicine (placebo) in people with early symptoms of AD.

2. Who can take part in the study?

People (males and females) of 50 - 90 years of age with AD can take part in the study if they have mild memory or thinking problems or if these problems have started to affect their work or daily activities. They also need to have confirmed presence of amyloid plaques in their brain, which will be checked through a brain scan (amyloid PET) or spinal tap (lumbar puncture). Participants must weigh 150 kg or less, and have someone serve as a study partner to support them during the study.

People may not be able to take part in this study if they have other brain conditions that could affect their thinking and memory, have conditions that affect the brain and its blood vessels, and/or have a history of certain mental health conditions. Those who cannot undergo an MRI scan will also be excluded. People who are pregnant, or currently breastfeeding cannot take part in the study. There may be additional criteria that people must meet, which can be determined after speaking with a study doctor.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place over 8 weeks before the start of treatment.

This is a 'placebo-controlled' study. This means that participants are put in a group that will receive a medicine or a group that will receive 'placebo' (a medicine that contains no active ingredients but looks the same and is taken in the same way as the study medicine). Comparing results from the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

Everyone who joins this study will be split into 2 groups randomly (like flipping a coin). Participants will be given either trontinemab or non-active medicine (placebo), through a drip into a vein (intravenous infusion). Participants will have an equal chance of being placed in either the trontinemab or placebo group.

This is a double-blinded study. This means that neither the participants in the study nor the team running it will know which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what people expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

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During this study, the study doctor will see participants. They will ask how participants are feeling and questions about their memory, conduct health examinations, and check for any unwanted effects participants may have. Participants will have one final visit during which the study doctor will check all measures assessed in the study and the participant's well being. Total time of participation in the study will be about 1 year and 7 months. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so. After this study ends, participants, if eligible, will be offered the option to join an open label extension study where everyone will receive trontinemab.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are changes in memory, thinking and daily functioning from the time when someone joins the study until week 72, using a specifically designed set of questions (questionnaires).

Other key results measured from study entry to week 72 using questionnaires and scoring tools include

- Changes in memory and thinking abilities
- Changes in the ability of the person to perform everyday activities
- Changes in focus and ability to follow instructions
- Brain protein buildup (amyloid and tau), and biomarkers in CSF and blood. A biomarker is a measurable indicator or sign that can be found in blood or bodily fluids that can indicate a health condition

Additionally, the number and seriousness of unwanted effects will also be measured.

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study assessments involve some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with the study medicine Participants may have unwanted effects of the medicine used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

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Trontinemab Participants will be told about the known unwanted effects of trontinemab, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines.

Trontinemab and placebo will be given as a drip into a vein (intravenous infusion). Known unwanted effects related to the infusion include symptoms such as fever and chills.

Known unwanted effects also include inflammation, swelling or small spots of bleeding in parts of the brain (Amyloid related imaging abnormalities, ARIA).

The study medicine may be harmful to an unborn baby. Women who might get pregnant must take precautions to avoid exposing an unborn baby to the study treatment.