ForPatients
by Roche

Alzheimer's Disease (AD)

A clinical trial to compare gantenerumab with placebo in people who are at risk for, or are in the earliest stages of, Alzheimer’s disease (AD)

A Study to Evaluate the Efficacy and Safety of Gantenerumab in Participants at Risk for or at the Earliest Stages of Alzheimer's Disease (AD)

Trial Status	Trial Runs In	Trial Identifier
Terminated	10 Countries	NCT05256134 2021-001184-25 WN42444

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

A study to evaluate the efficacy and safety of gantenerumab in amyloid-positive, cognitively unimpaired participants at risk for or at the earliest stages of AD. The planned number of participants for this study is approximately 1200 participants randomized in a 1:1 ratio to receive either gantenerumab or placebo (600 participants randomized to gantenerumab and 600 participants randomized to placebo).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT05256134 2021-001184-25 WN42444
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=60 Years & <= 80 Years	No

How does the SKYLINE (WN42444) clinical trial work?

This clinical trial is recruiting people who are at risk of developing, or are in the earliest stages of, Alzheimer’s disease (AD).

The purpose of this clinical trial is to compare the effects, good or bad, of gantenerumab versus placebo in people who are at risk of developing, or are in the earliest stages of,

AD. If you take part in this clinical trial, you will receive either gantenerumab or placebo. A ‘placebo’ medicine looks the same as the medicine in the clinical trial (active medicine) but does not contain any active ingredients.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be 60–80 years old and be at risk for developing AD or be in the earliest stages of AD (known as preclinical AD). You must be ‘amyloid positive’, which will be confirmed by either a scan of your brain, or by testing your cerebrospinal fluid, which will be obtained through a procedure known as a lumbar puncture. You must also demonstrate a certain level of brain function (be cognitively unimpaired) to join the clinical trial. Your doctor will confirm this through a number of tests that measure your brain health against certain criteria. You must also choose someone you are close with, for example a family member or friend, who you will have to contact (in person, by telephone, video call, email, or other electronic means) at least twice a week as your ‘study partner’. Your study partner will support you throughout the clinical trial and speak to your doctor about your abilities, such as logic and reasoning, attention, memory and processing information.

If you have been diagnosed with some pre-specified medical conditions, or have previously taken pre-specified medications, you may not be able to take part in this clinical trial.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, they may refer you to the closest clinical trial doctor. The clinical trial doctor will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

To take part, you must successfully go through the screening process, which lasts for approximately 17 weeks and includes some further tests to confirm this clinical trial is right for you. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial and for at least 17 weeks after the last dose of clinical trial treatment, women (who are not currently pregnant but can become pregnant, and who have not reached menopause) will need to either take contraceptive medicine or not have heterosexual intercourse for safety reasons.

What treatment will I be given if I join this clinical trial?

Everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin). You will have a 1 in 2 chance of receiving either gantenerumab or placebo.

The treatment period will be split into two parts: Part 1 and Part 2. You have up to Week 25 of the clinical trial to give your preference on how you would like to be given treatment in Part 2:

- One injection every week
- OR two injections once every two weeks.

In Part 1 (dose-escalation phase) you will be given either:

- Gantenerumab, as an injection under the skin once every four weeks for at least six months, then one injection every two weeks for three months (if you prefer one injection every week in Part 2) or two injections once every four weeks for three months (if you prefer two injections once every two weeks in Part 2)
    - Your dose will be gradually increased during this time
- OR placebo, as an injection under the skin once every four weeks for at least six months, then one injection every two weeks for three months (if you prefer one injection every week in Part 2) or two injections once every four weeks for three months (if you prefer two injections once every two weeks in Part 2).

Once your clinical trial treatmnet has been escalated to the target dose (the dose believed to have the best effect), you will enter Part 2 (maintenance phase) and you will be given either:

- Gantenerumab, as one injection under the skin every week or two injections under the skin once every two weeks, until the end of the four-year treatment period
- OR placebo, as one injection under the skin every week or two injections under the skin once every two weeks, until the end of the four-year treatment period.

Your first three doses in Part 1 will be administered by the clinical trial doctor. If you want to, you can then ask your clinical trial doctor if you, or your study partner, can administer your injections at home. You or your study partner will be given training by the clinical trial staff on how to do this and they will supervise you at your next four clinic visits to ensure this is being done appropriately. You may also have the option to have your injections administered by a home nurse.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a placebo. A placebo is used to show that the doctor or the participants do not sway the results of the clinical trial.

Neither you nor your clinical trial doctor can choose or know the group you are in, but you will be asked to take part in tests throughout the clinical trial to monitor how you are responding to treatment. If you are receiving placebo, have reached ‘target dose’ and show signs of progression due to AD, you will start to receive gantenerumab.

How often will I be seen in follow-up appointments and for how long?

You will be given the clinical trial treatment gantenerumab or placebo for roughly four years. You will have regular clinic visits every six months, which will include tests and brain scans to see how you are responding to the treatment and any side effects that you may be having. You are free to stop this treatment at any time. After the clinical trial, you will have a final clinic visit 16 weeks after your Week 211 safety and efficacy assessments.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for you, you will not be able to take part. Your doctor may suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT05256134