ForPatients
by Roche

Alzheimer's Disease (AD)

A clinical trial to look at the long-term effects of gantenerumab in people with Alzheimer’s disease

A Study to Evaluate the Safety and Tolerability of Long-term Administration of Gantenerumab in Participants With Alzheimer's Disease (AD)

Trial Status	Trial Runs In	Trial Identifier
Terminated	17 Countries	NCT04339413 WN41874

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

Trial Summary:

The main purpose of the study was to evaluate the safety and tolerability of long-term administration of gantenerumab in participants with AD. All participants who have completed the open-label extensions (OLEs) of studies WN25203 or WN28745 were enrolled in Part 1 of this study. Of these, participants who completed Week 104 visit in Part 1. Participants received open-label gantenerumab by subcutaneous (SC) injection every four weeks (Q4W) at the same dose as administered in the parent studies (part 1)/ Week 104 visit.

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

NCT04339413 WN41874
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	All	No

How does the Open RoAD clinical trial work?

This clinical trial has recruited people who have a type of disease called Alzheimer’s disease. In order to take part, they must have already completed one of the previous gantenerumab clinical trials, which were called WN25203 (SCarlet RoAD) and WN28745 (Marguerite RoAD).

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The purpose of this clinical trial is to evaluate the effects, good or bad, of long-term treatment with gantenerumab in people with Alzheimer's disease. In this clinical trial, you will be given gantenerumab only.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have already completed one of the previous gantenerumab clinical trials: WN25203 (SCarlet RoAD) or WN28745 (Marguerite RoAD). You must also have a caregiver who you will have regular contact with throughout the clinical trial.

You must not have left the previous trial before completion or stopped taking gantenerumab for any reason, and you cannot take part if you are pregnant.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your clinical trial doctor. They 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.

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, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or use contraceptive methods for safety reasons.

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

This clinical trial has been extended for an additional two years, and has now been split into two parts.

In Part 1, everyone who joined the clinical trial received gantenerumab, as an injection under the skin every four weeks for two years.

In Part 2, everyone who is still in the trial and completes Part 1 will be invited to continue their participation for an additional two years. In Part 2, you will continue to receive gantenerumab, as an injection under the skin every four weeks, for an additional two years.

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

In Part 1 of this clinical trial, you will have received gantenerumab every four weeks for two years. If you decide to continue your participation in Part 2 of the trial, you will be given gantenerumab every four weeks for an additional two years. You are free to stop this treatment at any time. If your treatment is stopped, you will be seen by the clinical trial doctor after four weeks. Information for this clinical trial will be collected from various assessments and tests that your doctor will carry out at each visit.

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 continue 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: NCT04339413

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