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 clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

An Open-Label, Multicenter, Rollover Study to Evaluate the Safety and Tolerability of Long-Term Administration of Gantenerumab in Participants With Alzheimer's Disease

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	Phase 3
Sponsor	Phase

NCT04339413 WN41874
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All		No

How does the Open RoAD clinical trial work?

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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).

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.

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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.

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

Inclusion Criteria:

- Part 1: Participants who completed the open-label extensions (OLEs) of studies WN25203 or WN28745 will be eligible to participate in Part 1 of the study
- Part 2: All participants who have completed Week 104 visit in Part 1 will be eligible for Part 2 of the study
- For Part 1 and Part 2:
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 16 weeks after the last dose of study drug
- Agreement to not donate blood or blood products for transfusion for the duration of the study and for 1 year after final dose of study drug
- Availability of a person ('caregiver') who in the investigator's judgement, has frequent and sufficient contact with the participant

Exclusion Criteria:

- Prematurely discontinued from the OLEs of studies WN25203 or WN28745 or from study drug for any reason

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- Any medical condition that may jeopardize the participant's safety if he or she continues to receive study treatment
- If the participant is unlikely to benefit from gantenerumab therapy, based on disease progression or other factors, or if study participation is otherwise not in the participant's best interest
- Any investigational treatment other than gantenerumab during or since completion of the OLEs of studies WN25203 or WN28745
- Pregnancy
- Evidence of disseminated leptomeningeal hemosiderosis (i.e., more than three focal leptomeningeal hemosiderosis)
- Evidence of intracerebral macrohemorrhage
- Part 2: Participants who have been discontinued from Part 1 of the study

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