ForPatients
by Roche

Alzheimer's Disease (AD)

A clinical trial to look at the safety and effects of long-term treatment with gantenerumab in people with Alzheimer's disease

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

Trial Status	Trial Runs In	Trial Identifier
Terminated	29 Countries	NCT04374253 2020-000766-42 WN42171

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

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

Trial Summary:

This is an open-label, multicenter, rollover study to evaluate the safety, tolerability, and efficacy of long-term administration of open-label gantenerumab in participants with AD who completed Study WN29922 or WN39658, either the double-blind or open-label extension (OLE) part.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04374253 2020-000766-42 WN42171
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	lblAllAges	No

How does the WN42171 clinical trial work?

This clinical trial is recruiting people who have Alzheimer’s disease. In order to take part, patients must have completed one of two previous studies, either study WN29922 or study WN39658.

The purpose of this clinical trial is to measure the long-term safety and effects of gantenerumab for people in these studies. All participants in this study will receive gantenerumab.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed with Alzheimer's disease and you must have taken part in either study WN29922 or study WN39658. You cannot take part if you discontinued study WN29922 or study WN39658 early, or if you received any other experimental treatment for Alzheimer's disease after finishing one of these studies.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. They will give you all the information you need to make your decision about taking part in the clinical trial.

You may have some further tests to make sure you will be able to take the treatments given in this clinical trial. 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 in either study WN29922 or study WN39658, 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, women who are not currently pregnant but could become pregnant will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

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

Everyone who joins this clinical trial will receive gantenerumab, given as an injection under the skin every two weeks. You will be given treatment in the same way as you received treatment in study WN29922 or study WN39658, meaning that you won't be able to tell whether you previously received gantenerumab or placebo

Sub-studies

Some people who join this clinical trial may also be able to take part in a 'sub-study'. This clinical trial currently has two sub-studies, which aim to study two different proteins that are involved in Alzheimer's disease, known as amyloid and tau.

Patients who participate in the sub-studies will have up to three brain scans (called Positron Emission Tomography, or PET scans) during the study. Before each PET scan, patients will receive an injection with a small amount of ‘tracer’, which binds to particular proteins so that researchers can see them on the PET scan. Patients in the amyloid sub-study will receive one of two tracers, called florbetaben or flutemetamol. Patients in the tau sub-study will receive a tracer called [18F]GTP1.

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

You will be given gantenerumab every 2 weeks for up to 2 years. Treatment visits will include checks 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 being given your last dose, you will have a follow-up appointment with the clinical trial doctor after 2 weeks and then a final visit after about 3 months.

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 will 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: NCT04374253

Inclusion Criteria:

- Completed Study WN29922 or WN39658, either its double-blind part or OLE part, and did not discontinue study drug early
- The participant should be capable of completing assessments either alone or with the help of the caregiver
- Availability of a person (referred to as the "caregiver")
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception methods with a failure rate of <1% per year (bilateral tubal ligation, male sterilization, hormonal contraceptives that inhibit ovulation, hormone-releasing intrauterine devices, and copper intrauterine devices) during the treatment period and for at least 16 weeks after the final dose of gantenerumab
- Agreement not to donate blood or blood products for transfusion for the duration of the study and for 1 year after final dose of study drug

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within at least 16 weeks after the final dose of study drug
- Prematurely discontinued from Study WN29922 or WN39658
- Any medical condition that may jeopardize the participant's safety if he or she continues to receive study treatment

- Received any investigational treatment other than gantenerumab during or since completion of Study WN29922 or WN39658, either its double-blind or OLE part
- Evidence of disseminated leptomeningeal hemosiderosis
- Evidence of intracerebral macrohemorrhage
- Use of prohibited medication
- Evidence of ARIA-E on the last MRI scan report in Study WN29922 or WN39658, either its double-blind or OLE part