ForPatients
by Roche

Alzheimer's Disease (AD)

A clinical trial to look at the effects of gantenerumab on the body in people with early Alzheimer’s disease

A Study to Evaluate the Pharmacodynamic (PD) Effects of Once Weekly Administration of Gantenerumab in Participants With Early Alzheimer's Disease (AD)

Trial Status	Trial Runs In	Trial Identifier
Terminated	8 Countries	NCT04592341 2020-001384-87 WN29722

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:

A Phase II, Multicenter, Open-Label, Single Arm Study to Evaluate the Pharmacodynamic Effects of Once Weekly Administration of Gantenerumab in Participants With Early (Prodromal to Mild) Alzheimer's Disease

Trial Summary:

This is a Phase II, multicenter, open-label, single arm, PD study in participants with early (prodromal to mild) AD to evaluate the effect of a once weekly (Q1W) dosing regimen of gantenerumab on deposited amyloid as measured by change from baseline to Week 104 (primary) and Week 208 in brain amyloid positron emission tomography (PET). The administration of gantenerumab as a single injection of Q1W will be investigated in this study, to simplify the dosing regimen for participants.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT04592341 2020-001384-87 WN29722
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years & # 90 Years	No

How does the WN29722 clinical trial work?

This clinical trial is recruiting people who have Alzheimer’s disease. In order to take part, patients must have an early form of the disease.

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The purpose of this clinical trial is to test the effects, good or bad, of gantenerumab on the body.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must be 50–90 years of age with early Alzheimer's disease (also referred to as prodromal or mild) that has been diagnosed from the results of a brain amyloid positron emission tomography (PET) scan. You should also have a person willing to be your 'study partner'. This person should be someone who knows you well and spends a lot of time with you, such as a spouse, partner or other family member, and who can attend clinic visits with you.

You must not have any condition other than Alzheimer's disease that affects the central nervous system. You may not be able to take part if you have been previously diagnosed with certain medical conditions.

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, he/she may refer you to the closest 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.

You will 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.

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 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 be given gantenerumab as an injection under the skin of the stomach.

The frequency of injections and the dose of gantenerumab will be gradually increased for up to 9 months until the target dose of 255 mg every week is achieved.

Gantenerumab will be given as follows:

- For the first 3 doses (up to Week 8): 1 injection (120 mg) every 4 weeks
- For the next 3 doses (up to Week 20): 1 injection (255 mg) every 4 weeks

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- For the next 6 doses (up to Week 34): 1 injection (255 mg) every 2 weeks
- For the rest of the study (up to Week 103): 1 injection (255 mg) every week

You can also choose to take part in a 2-year extension of the clinical trial, and you will be given gantenerumab for an additional 2 years (up to Week 207): 1 injection (255 mg) every week.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment gantenerumab for approximately 2 years (103 weeks). If you take part in the 2-year extension, you will be given gantenerumab for approximately 4 years (207 weeks). You are free to stop this treatment at any time. You are free to stop this treatment at any time.

During the treatment period, you will have regular contact with the study staff, through clinic visits and/or telephone calls. These visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

You will have several PET scans during the trial including at screening (before you start treatment), and at Weeks 52 and 104. If you choose to take part in the 2-year extension of the trial, you will also have PET scans at Weeks 156 and 208. Before these scans, you will receive an injection of a tracer.

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: NCT04592341

Inclusion Criteria:

- Probable Alzheimer's Disease (AD) dementia or prodromal AD.
- Availability of a reliable study partner (non-professional caregiver) who accepts to participate in study procedure throughout the study duration
- The participant should be capable of completing all aspects of study assessments including MRI, clinical genotyping, and PET imaging, either alone or with the help of the study partner (non-professional caregiver).
- Adequate visual and auditory acuitysufficient to perform the neuropsychological testing (eye glasses and hearing aids are permitted).
- Evidence of AD pathological process, as confirmed by amyloid PET scan by qualitative read by the core/central PET laboratory.
- Prodromal or mild symptomatology, as defined by a screening Mini-Mental State Examination (MMSE) score >/=22 and Clinical Dementia Rating global score (CDR-GS) of 0.5 or 1.0, as well as a clinical dementia rating (CDR) memory domain score >/=0.5.

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- If the participant is receiving symptomatic AD medications, a stable dosing regimen for at least 3 months prior to screening and until start of study treatment.
- 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.
- Agreement not to participate in other research studies for the duration of this trial, unless these are related Roche-sponsored non-interventional studies.
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods hat result in a failure rate of < 1% per year during the treatment period and for at least 16 weeks after the final dose of study drug.

Exclusion Criteria:

- Any evidence of a condition other than AD that may affect cognition.
- History or presence of clinically evident systemic vascular disease that in the opinion of the investigator has the potential to affect cognitive function.
- History or presence of clinically evident cerebrovascular disease.
- History or presence of posterior reversible encephalopathy syndrome.
- History or presence of any stroke with clinical symptoms within the past 12 months, or documented history within the last 6 months of an acute event that is consistent with a transient ischemic attack.
- History of severe, clinically significant CNS trauma.
- History or presence of intracranial mass that could potentially impair cognition.
- Presence of infections that affect brain function or history of infections that resulted in neurologic sequelae.
- History or presence of systemic autoimmune disorders that potentially cause progressive neurologic disease with associated cognitive deficits.
- History of schizophrenia, schizoaffective disorder, major depression, or bipolar disorder.
- At risk for suicide in the opinion of the investigator.
- Alcohol and/or substance abuse or dependants in past 2 years.

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