ForPatients
by Roche

Enfermedad de Alzheimer (EA)

WN41874 Estudio para evaluar la seguridad y tolerabilidad de la administración a largo plazo de gantenerumab en participantes con enfermedad de Alzheimer (AD) (OPEN ROAD)

Estudio multicéntrico, abierto, de transferencia para evaluar la seguridad y tolerabilidad de la administración a largo plazo de gantenerumab en participantes con enfermedad de Alzheimer

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

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

Estudio multicéntrico, abierto, de transferencia para evaluar la seguridad y tolerabilidad de la administración a largo plazo de gantenerumab en participantes con enfermedad de Alzheimer

Trial Summary:

Este es un estudio multicéntrico, abierto, de transferencia para evaluar la seguridad y tolerabilidad de la administración a largo plazo de gantenerumab en participantes con AD. Todos los participantes que hayan completado las extensiones abiertas (OLE) de los estudios WN25203 o WN28745 serán elegibles para participar en este estudio. Los participantes seguirán recibiendo gantenerumab de manera abierta mediante inyección subcutánea (SC) cada cuatro semanas (C4S) con la misma dosis que se administró en los estudios principales.

Hoffmann-La Roche	Fase 3
Sponsor	Phase

NCT04339413 WN41874
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All		No

1. How does the WN41874 clinical trial work?

This clinical trial is recruiting people who have a type of disease called Alzheimer's disease. In order to take part, people 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 gantenerumab on people with Alzheimer's disease. In this clinical trial, you will be given gantenerumab only.

2. 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, which were called WN25203 (SCarlet RoAD) and WN28745 (Marguerite RoAD).

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.

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

Everyone who joins this clinical trial will receive gantenerumab, which is given as an injection under your skin every 4 weeks for 2 years.

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

You will be given the clinical trial treatment gantenerumab every 4 weeks for 2 years. You are free to stop this treatment at any time. After being given treatment, you will be seen by the clinical trial doctor 4 weeks after your treatment has stopped. Information for this study will be collected from assessments and tests that your doctor will carry out at each visit.

5. 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 < https://clinicaltrials.gov/ct2/show/NCT04339413>

Trial-identifier: NCT04339413

Inclusion Criteria:

- Participantes que completaron las extensiones abiertas (OLE) de los estudios WN25203 o WN28745
- Para las mujeres con capacidad de concebir: aceptación de permanecer en abstinencia (abstenerse de tener relaciones heterosexuales) o usar métodos anticonceptivos con una tasa de fracaso de menos del 1 % al año durante el período del tratamiento y por lo menos 16 semanas después de la dosis final del medicamento del estudio

Exclusion Criteria:

- Interrupción anticipada de las OLE de los estudios WN25203 o WN28745, o del medicamento del estudio por cualquier razón
- Cualquier afección médica que ponga en riesgo la seguridad del participante si él/ella continúa recibiendo el tratamiento del estudio.
- Si es improbable que el participante se beneficie de la terapia con gantenerumab, con base en la progresión de la enfermedad u otros factores, o si la participación en el estudio no es lo más conveniente para el participante.
- Cualquier tratamiento en investigación distinto de gantenerumab durante o después de la finalización de las OLE de los estudios WN25203 o WN28745
- Embarazo
- Evidencia de hemosiderosis leptomeníngea diseminada (es decir, más de tres hemosiderosis leptomeníngeas focales)
- Evidencia de macrohemorragia intracerebral