

Degeneración Macular Senil Húmeda

GR40306 Estudio para evaluar la eficacia y seguridad de Faricimab en participantes con degeneración macular neovascular relacionada con la edad (TENAYA)

Estudio de fase III, multicéntrico, aleatorizado, con doble enmascaramiento, controlado con comparador activo para evaluar la eficacia y seguridad de Faricimab en pacientes con degeneración macular neovascular relacionada con la edad (TENAYA)

Trial Status
Finalizado

Trial Runs In
15 Countries

Trial Identifier
NCT03823287 2018-002152-32
GR40306

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:

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Trial Summary:

Este estudio evaluará la eficacia, seguridad, durabilidad y farmacocinética de faricimab administrado en intervalos según las especificaciones del protocolo, en comparación con aflibercept una vez cada 8 semanas (Q8W), en participantes con degeneración macular neovascular relacionada con la edad (nAMD).

Hoffmann-La Roche
Sponsor

Fase 3
Phase

NCT03823287 2018-002152-32 GR40306
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#50 Years

Healthy Volunteers
No

How does the TENAYA clinical trial work?

This clinical trial is recruiting people who have a type of eye disease called neovascular age-related macular degeneration, or nAMD.

The purpose of this clinical trial is to compare the effects, good or bad, of faricimab versus aflibercept in patients with nAMD. In this clinical trial, you will get either faricimab or aflibercept as treatment.

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 nAMD.

If you have previously been treated for nAMD in the study eye or been given faricimab in either eye, have uncontrolled blood pressure or other eye related problems, you will not be able to join the trial.

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. If you have had some of the tests recently, 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, both men and 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 split into 1 of 2 groups randomly (like flipping a coin) and given either:

- faricimab, given as an injection into your eye (the time between injections will be based on how your disease responds to the treatment and will vary throughout the trial)
- OR aflibercept, given as an injection into your eye every 4 weeks for the first 3 months, and then every 8 weeks until the end of the trial

ForPatients

by Roche

You will have an equal chance of being placed in any group. Only one eye will be treated during the study. If you have nAMD in both eyes, the eye that has the worst vision will be treated with the clinical trial drug and you will be given the current standard treatment for your other eye.

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk. You will have to see the clinical trial doctor every 4 weeks. As the times between treatments are different for each group, you will have to have a sham treatment during the visits where you do not need your treatment to make sure that nobody knows which group you are in.

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

You will be given the clinical trial treatment faricimab OR aflibercept for just over 2 years (108 weeks). You are free to stop this treatment at any time. After being given your last treatment, you will be seen once more by the clinical trial doctor after 4 weeks. This hospital visit will include checks to see how you are responding to the treatment and monitor any side effects that you may be having.

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/NCT03823287>

Trial-identifier: NCT03823287

Inclusion Criteria:

- Neovascularización coroidea (CNV) sin tratamiento previo secundaria a la degeneración macular relacionada con la edad (nAMD) en el ojo del estudio
- Capacidad para cumplir con el protocolo del estudio, según el criterio del investigador.

- Para mujeres con capacidad de concebir: acuerdo de permanecer abstinentes (abstenerse de tener relaciones heterosexuales) o usar medidas anticonceptivas aceptables que resulten en una tasa de falla <1% por año durante el tratamiento
- Se pueden aplicar otros criterios de inclusión especificados en el protocolo.

Exclusion Criteria:

- Presión arterial no controlada, definida como presión arterial sistólica > 180 milímetros de mercurio (mmHg) y/o presión arterial diastólica > 100 mmHg mientras un paciente está en reposo el día 1
- Embarazo o lactancia, o intención de quedar embarazada durante el estudio
- CNV debida a causas distintas de la AMD en el ojo del estudio
- Cualquier antecedente de patología macular no relacionada con la AMD que afecte la visión o que contribuya a la presencia de líquido intrarretiniano o subretiniano en el ojo del estudio
- Cualquier condición intraocular concurrente en el ojo del estudio que, en opinión del investigador, podría reducir el potencial de mejora visual o requerir intervención médica o quirúrgica durante el estudio.
- Glaucoma no controlado en el ojo del estudio.
- Cualquier tratamiento previo o concomitante para la CNV o anormalidades de la interfaz vitreomacular en el ojo del estudio.
- Administración IVT previa de faricimab en cualquier ojo
- Antecedente de uveítis idiopática o asociada con problemas autoinmunes en cualquier ojo
- Inflamación ocular activa o infección ocular o periocular sospechada o activa en cualquier ojo
- Se pueden aplicar otros criterios de exclusión especificados por el protocolo.