ForPatients
by Roche

Degeración macular asociada a la edad (DMAE) húmeda

Estudio para evaluar eficacia y seguridad de Faricimab en pacientes con Degeneración macular asociada a la edad Neovascular (TENAYA)

Trial Status	Trial Runs In	Trial Identifier
Completado	15 Countries	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:

Estudio de fase III, multicéntrico, randomizado, con doble enmascaramiento, controlado con comparador activo, para evaluar la eficacia y la seguridad de faricimab en pacientes con degeneración macular asociada a la edad neovascular (TENAYA).

Trial Summary:

Este estudio evaluará la eficacia, la seguridad, la durabilidad y la farmacocinética del faricimab administrado a intervalos como se especifica en el protocolo, en comparación con el aflibercept una vez cada 8 semanas (Q8W), en participantes con degeneración macular neovascular relacionada con la edad (nAMD).

Hoffmann-La Roche
Sponsor

Fase III
Phase

NCT03823287 2018-002152-32 GR40306
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	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

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:

- Edad >= 50 años.
- Ser capaces de cumplir los requisitos del protocolo del estudio.
- Las mujeres potencialmente fértiles deben comprometerse a practicar la abstinencia sexual o a usar métodos anticonceptivos, durante el período de tratamiento y como mínimo, hasta 3 meses después de la administración de la última dosis del tratamiento del estudio.
- No haber recibido previamente tratamiento para la neovascularización coroidea (NVC) secundaria a DMAE (DMAEn) en el ojo a estudio.
- MAVC de 20/32 a 20/320 (de 78 a 24 letras) en el ojo a estudio al inicio del tratamiento.

Exclusion Criteria:

- Presión arterial no controlada.
- Mujeres embarazadas, en período de lactancia o que tengan intención de quedarse embarazadas durante el estudio.
- NVC por causas distintas de DMAE en el ojo a estudio.
- Antecedentes de cualquier patología macular no relacionada con la DMAE que afecte a la visión o contribuya a la presencia de líquido intrarretiniano o subretiniano en el ojo a estudio.
- Presencia de coriorretinopatía serosa central en la visita de selección.
- Desgarro del epitelio pigmentario retiniano que afecte a la mácula, el día 1 en el ojo a estudio.
- Evidencia de lo siguiente en AF/CFP:
    - Hemorragia subretiniana en > 50% del área total de la lesión y/o que afecte a la fóvea.
    - Fibrosis o atrofia en > 50% del área total de la lesión y/o que afecte a la fóvea.
- Cualquier afección intraocular concurrente en el ojo a estudio que, en opinión del investigador, pudiera reducir el potencial de mejoría visual o requerir intervención médica o quirúrgica durante el estudio.
- Hemorragia vítrea presente el día 1 en el ojo a estudio.
- Glaucoma no controlado en el ojo a estudio.
- Equivalente esférico del error refractivo que demuestre miopía de más de 8 dioptrías en el ojo a estudio.
- Cualquier tratamiento previo o concomitante para la NVC o anomalías de la interfase vitreomacular en el ojo a estudio.
- Cualquier cirugía para cataratas o tratamiento con esteroides o capsulotomía con láser YAG para las complicaciones de la cirugía para cataratas en el ojo a estudio en los 3 meses previos al día 1.
- Cualquier otra cirugía intraocular en el ojo a estudio.
- Tratamiento previo farmacológico o IVT periocular para otras enfermedades retinianas.
- Administración previa de faricimab IVT en cualquier ojo.
- Inflamación ocular activa o infección ocular o periocular presuntiva o activa en cualquier ojo el día 1.