ForPatients
by Roche

Neovascular Age-related Macular Degeneration

A study to look at how well faricimab works to treat neovascular age-related macular degeneration when there is a longer amount of time between injections

A Study to Determine the Efficacy, Safety, and Durability of Faricimab in Participants With Neovascular Age-Related Macular Degeneration

Trial Status	Trial Runs In	Trial Identifier
Recruiting	12 Countries	NCT06795048 2024-517545-13-00 MR45638

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 IIIb/IV, Multicenter, Randomized, Open-Label, Two-Arm Study to Investigate the Efficacy, Safety, and Durability of Faricimab Administered up to Every 24 Weeks in Patients With Neovascular Age-Related Macular Degeneration

Trial Summary:

This study is a Phase IIIb/IV, multicenter, randomized, two-arm, open-label 100-week study to investigate the efficacy, safety, and durability of intravitreal 6-mg faricimab administered at up to 24-week intervals in patients with neovascular age-related macular degeneration (nAMD) that are treatment-naïve in the study eye.

Hoffmann-La Roche	Phase 4
Sponsor	Phase

NCT06795048 2024-517545-13-00 MR45638
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

1. Why is this study needed?

Neovascular (or wet) age-related macular degeneration (nAMD) is a medical condition where unhealthy blood vessels grow in the central area at the back of the eye. These vessels cause swelling and bleeding at the back of the eye. This can lead to vision loss.

nAMD can be treated with medicines such as faricimab, which is designed to block growth of abnormal blood vessels and the leakage of fluid from them. Faricimab is approved by health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) for the treatment of nAMD.

Faricimab is given as injections into the eye, also known as intravitreal (IVT) injections. When starting treatment, frequent IVT injections are required - every month for 4 months, then the treatment interval can be extended to every 4 months or more frequently if needed. This can be a burden for people with nAMD.

This study aims to test if the disease can be controlled and vision can be improved with fewer injections of faricimab.

2. Who can take part in the study?

People of at least 50 years of age with nAMD can take part in the study if they have not yet been given any treatment for nAMD in one eye, and have eyes clear enough so that photographs of the back of their eyes can be taken.

People may not be able to take part in this study if they have other certain medical conditions such as another eye condition, uncontrolled high or low blood pressure, or cancer within the previous year. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 1 month before the start of treatment.

Everyone who joins this study will be placed into 1 of 2 groups. Participants will have an equal chance of being placed in either group. One group will be given the first monthly faricimab injections for longer than the other group. After the monthly doses, the study doctor can adjust the amount of time between IVT injections. This will depend on the participants' vision and eye health. The amount of time between IVT injections may be increased, decreased or kept the same.

Participants will be given:

- Faricimab, given as IVT injections once a month to begin, then every 1 to 6 months as needed

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants regularly every 1 to 6 months. They will see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit 1 month after their final dose of study treatment, during which the study doctor will check on the participant's wellbeing. Total time of participation in the study will be about 2 years. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked is how much vision changes from the start of the study, averaged over Months 10, 11 and 12. Vision is measured using the 'best-corrected visual acuity' score - the best eyesight a person can have when using glasses or contact lenses.

Other key results measured in the study include:

- Average change in vision over Months 21, 22 and 23 and throughout the study
- The number of participants whose vision improves, stays the same or gets worse
- Average change in the thickness of the back of the eye (retina) since the start of the study at 10 to 12 months, 21 to 23 months, and throughout the study
- The number of participants at 1 and 2 years after starting treatment who need IVT injections every 1, 2, 3, 4, 5 or 6 months
- The number and seriousness of unwanted effects

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not improve participants' eye health and vision. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with faricimab or the IVT injection Participants may have unwanted effects of the medicine or injection procedure used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Participants will be told about the known unwanted effects of faricimab or the IVT injections, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include the lens of the eye becoming cloudy (cataract), higher pressure in the eye than usual for a short time, eye pain, and dots and lines in vision caused by changes to the gel-like substance inside the eye.

The study medicine(s) may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.

Inclusion Criteria:

- Overtly healthy as determined by medical evaluation that includes medical history and physical examination
- Agreement to adhere to the contraception requirements described in the protocol

Ocular Inclusion Criteria for Study Eye:

- Active treatment-naïve macular neovascularization (MNV) secondary to age-related macular degeneration (AMD), confirmed by the investigator based on the presence of intraretinal fluid (IRF) or subretinal fluid (SRF) affecting the central subfield on optical coherence tomography (OCT)
- BCVA of 83 to 24 letters, inclusive (20/25 to 20/320 approximate Snellen equivalent, using the early treatment diabetic retinopathy study [ETDRS] protocol and addressed at the initial testing distance of 4 meters on Day 1)
- Sufficiently clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal images to confirm diagnosis

Exclusion Criteria:

Ocular Exclusion Criteria for Study Eye:

- MNV due to causes other than nAMD, such as ocular histoplasmosis, trauma, pathological myopia, angioid streaks, choroidal rupture, or uveitis
- Retinal pigment epithelial tear involving the macula on Day 1
- Current vitreous hemorrhage on Day 1
- Prior periocular pharmacological or IVT treatment (including faricimab, anti-vascular endothelial growth factor [VEGF], or complement inhibitor medication) for other retinal diseases

Ocular Exclusion Criteria for Fellow (Non-Study) Eye:

- Participants who have a nonfunctioning fellow (non-study) eye, defined as either BCVA of hand motion or worse, or no physical presence of non-study eye (i.e., monocular), at both the screening and study Day 1 visits

Ocular Exclusion for Both Eyes:

- History of idiopathic or autoimmune associated uveitis in either eye

- Active ocular inflammation or suspected or active ocular or periocular infection in either eye on study Day 1