

Neovascular Age-related Macular Degeneration Age-Related Macular Degeneration

A clinical trial to look at the long-term safety of faricimab in patients with neovascular age-related macular degeneration (nAMD, also known as wet AMD)

A Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Participants With Neovascular Age-Related Macular Degeneration

Trial Status
Active, not recruiting

Trial Runs In
27 Countries

Trial Identifier
NCT04777201 2020-004523-16
GR42691

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This main long-term extension study is designed to evaluate the long-term safety and tolerability of faricimab 6 milligrams (mg) administered by intravitreal injection at a personalized treatment interval (PTI) to participants with neovascular age-related macular degeneration (nAMD) who enrolled in and completed one of the Phase III studies: GR40306 (NCT03823287) or GR40844 (NCT03823300), also referred to as the parent studies. Eligible patients who consent to participate in this main study will be enrolled upon completion of the end-of-study visit in the parent study. Additionally, there is a substudy that is being conducted. The aim of this substudy is to evaluate the impact of intravitreal faricimab on the health of the corneal endothelial cells in the study eyes of patients with nAMD to fulfill a U.S. Food and Drug Administration (FDA) post-marketing requirement. The fellow eyes of the same enrolled participants in the substudy will serve as the controls.

Hoffmann-La Roche
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Phase 3
Phase

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Eligibility Criteria:

Gender
All

Age
≥50 Years

Healthy Volunteers
No

How does the Avonelle-X (GR42691) clinical trial work?

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This clinical trial is recruiting people who have neovascular age-related macular degeneration (nAMD, also known as wet AMD) and who previously participated in and completed either Study GR40306 (also known as TENAYA) or GR40844 (also known as LUCERNE).

The purpose of this clinical trial is to learn more about the effects, good or bad, of long-term use of the study treatment, faricimab, on patients with nAMD. If you take part in this clinical trial, you will receive faricimab.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have previously participated in and completed either Study GR40306 (also known as TENAYA) or GR40844 (also known as LUCERNE), without stopping the study treatment or the trial.

If you have other conditions or need to take any other medications, you may not be able to take part.

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, women (who are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons. Women must not donate eggs while taking part in the clinical trial.

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

This clinical trial is split into two parts.

In Part 1 (the masked phase), everyone who joins this clinical trial will be given faricimab as an injection into the study eye. You will have study visits every four weeks for roughly

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12 weeks but how often you receive injections will vary, depending on the condition of your eye. If a faricimab injection is not scheduled at a particular visit, you will have a “sham” treatment designed to feel like a real injection instead (an empty syringe without a needle will be pressed against your numbed eye).

Neither you nor your clinical trial doctor will know whether you are receiving faricimab or sham treatment at each visit. However, your clinical trial doctor can find out how often you are receiving study treatment if your safety is at risk.

In Part 2 (the open-label phase), you will only have study visits when you need a faricimab injection. You will receive faricimab either every 8, 12 or 16 weeks, depending on the condition of your eye.

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

You will be given the study treatment, faricimab, for roughly 2 years. You are free to stop this treatment at any time. While being given treatment, you will still be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and to 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/NCT04777201>

Trial-identifier: NCT04777201