ForPatients
by Roche

Diabetic Macular Edema

A clinical trial to look at the long-term safety and effects of faricimab for people with diabetic macular edema (RHONE-X)

A Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Participants With Diabetic Macular Edema

Trial Status	Trial Runs In	Trial Identifier
Completed	31 Countries	NCT04432831 2020-000402-29 GR41987

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 is a multicenter long-term extension study designed to evaluate the long-term safety and tolerability of faricimab administered by intravitreal (IVT) injection at a personalized treatment interval (PTI) to participants who enrolled in and completed one of the two Phase III studies, GR40349 (NCT03622580) or GR40398 (NCT03622593), also referred to as the parent studies.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04432831 2020-000402-29 GR41987
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the RHONE-X clinical trial work?

This clinical trial is recruiting people who have a type of disease called diabetic macular edema. In order to take part, patients must have taken part in and completed either study GR40349 (also called ‘YOSEMITE’) or study GR40398 (also called ‘RHINE’). The purpose of this clinical trial is to test the long-term safety of faricimab for patients who have finished either of these two clinical trials.

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 diabetic macular edema and completed either study GR40349 (YOSEMITE') or study GR40398 ('RHINE'). If you are pregnant or breast feeding, you will 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 clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial.

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.

What treatment will I be given if I join this clinical trial?
Everyone in this study will receive faricimab, given as an injection into the eye.

During the first 4 months of this trial, everyone will come for a monthly visit to receive either a faricimab injection or a sham procedure. A sham procedure uses the blunt end of an empty syringe (without a needle) and presses it against the anesthetized eye to simulate a real injection. The sham procedures are to help people transition from their previous treatment on the YOSEMITE or RHINE trials.

This first 4-month period of this trial is 'masked'. This means that you will not know whether you are receiving faricimab or sham. After the first 4 months, the trial is 'open label'. This means you will receive faricimab at a personalised treatment interval, where the number of visits and how frequently you receive injections will be calculated by the clinical trial doctor.

How often will I be seen in follow-up appointments and for how long?
You will be given faricimab at a personalised treatment interval for as long as it can help you. You are free to stop this treatment at any time. After being given treatment, you may still be contacted by the clinical trial doctors to check for any side effects you may be having.

What happens if I am unable to take part in this clinical trial?

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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/NCT04432831
Trial-identifier: NCT04432831