

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 Completed	Trial Runs In 30 Countries	Trial Identifier NCT04432831 2020-000402-29 GR41987
----------------------------------	--------------------------------------	--

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 Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Patients With Diabetic Macular Edema

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 All	Age #18 Years	Healthy Volunteers 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

ForPatients

by Roche

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?

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

Inclusion Criteria:

- Previous enrollment in and completion of Study GR40349 (NCT03622580) or GR40398 (NCT03622593), without study or study drug discontinuation
- Ability to comply with the study protocol, in the investigator's judgment
- For women of childbearing potential: agreement to remain abstinent or use acceptable contraceptive methods that result in a failure rate of <1% per year during the treatment period and for at least 3 months after the final dose of study treatment

Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final intravitreal injection of faricimab
- Presence of other ocular diseases that give reasonable suspicion of a disease or condition that contraindicates the use of faricimab, that might affect interpretation of the results of the study or that renders the patient at high risk for treatment complications
- Presence of other diseases, metabolic dysfunction, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of faricimab and that might affect interpretation of the results of the study or that renders the patient at high risk of treatment complications
- History of a severe allergic reaction or anaphylactic reaction to a biologic agent or known hypersensitivity to any component of the faricimab injections, study treatment procedure, dilating drops, or any of the anesthetic and antimicrobial preparations used by a patient during the study
- Requirement for continuous use of any medications or treatments indicated as prohibited therapy