ForPatients
by Roche

Diabetic Macular Edema

A clinical trial to look at new ways of measuring how faricimab works in patients with diabetic macular edema

A Study to Investigate Aqueous Humor and Multimodal Imaging Biomarkers in Treatment-Naïve Participants With Diabetic Macular Edema Treated With Faricimab

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT04597918 2020-001174-30 MR41926

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 an exploratory, prospective, multicenter, open-label, single-arm, interventional, Phase IIb study designed to explore the associations over time between clinical assessments, multimodal imaging assessments, aqueous humor (AH) biomarker patterns, and genetic polymorphisms in participants with diabetic macular edema (DME) who are treated with faricimab.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT04597918 2020-001174-30 MR41926
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the ALTIMETER clinical trial work?

This clinical trial is recruiting people who have a type of diabetic eye disorder. In order to take part, patients must have diabetic macular edema.

The purpose of this clinical trial is to look at new ways to measure the effect of faricimab in patients with diabetic macular edema. 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 been diagnosed with diabetic macular edema due to diabetes mellitus (Type I or Type II) and you must be at least 18 years old.

You cannot join the trial if you are pregnant or breastfeeding. You must not have received any previous treatment for the study eye (the one receiving treatment), including laser treatments, injection-based treatments, corticosteroids or compounds that block VEGF.

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 (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 given faricimab, given as an injection into the study eye, every 4 weeks for around 20 weeks.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment faricimab for approximately 20 weeks up to a maximum of 6 treatments. You are free to stop this treatment at any time. Before your first and fifth treatment, doctors will take a small sample of fluid from your eye to check for any changes. You will also be seen regularly by the clinical trial doctor every 4 weeks until you complete treatment, and then around 4 to 5 weeks after your last injection. These hospital visits will include checks to see how you are responding to the treatment and 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.

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For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

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