ForPatients
by Roche

Central Retinal Vein OcclusionRetinal Vein OcclusionHemiretinal Vein OcclusionMacular Edema

A clinical trial to compare faricimab with aflibercept in people with macular oedema due to blockage of the central (main) retinal vein or the hemiretinal vein (main branch of the smaller blood vessels) within the eye

A Study to Evaluate the Efficacy and Safety of Faricimab in Participants With Macular Edema Secondary to Central Retinal or Hemiretinal Vein Occlusion

Trial Status	Trial Runs In	Trial Identifier
Completed	22 Countries	NCT04740931 2020-000441-13 GR41986

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 III, Multicenter, Randomized, Double-Masked, Active Comparator-Controlled Study to Evaluate the Efficacy and Safety of Faricimab in Patients With Macular Edema Secondary to Central Retinal or Hemiretinal Vein Occlusion

Trial Summary:

This is a Phase III, multicenter, randomized, double-masked, active comparator-controlled, parallel-group study evaluating the efficacy, safety, and pharmacokinetics of faricimab administered by intravitreal (IVT) injection at 4-week intervals until Week 24, followed by a double-masked period of study without active control to evaluate faricimab administered according to a personalized treatment interval (PTI) dosing regimen in patients with macular edema due to central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO).

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04740931 2020-000441-13 GR41986
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the COMINO clinical trial work?

This clinical trial is recruiting people who have macular oedema (swelling within the macula part of the eye) that is caused by central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). CRVO means that all of the branches of the central retinal vein in the eye have become blocked and HRVO means that half of the branches of the central retinal vein have become blocked. CRVO and HRVO can cause fluid to leak into the macula. This build-up of fluid causes swelling that can affect vision.

The purpose of this clinical trial is to compare the effects, good or bad, of faricimab against aflibercept in patients with macular oedema due to CRVO or HRVO. If you take part in this clinical trial, you will receive either faricimab or aflibercept for the first 20 weeks, followed by faricimab for a further 48 weeks.

Faricimab blocks the two important pathways that are thought to be involved in CRVO and HRVO: vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2). Aflibercept blocks VEGF only.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with macular oedema due to CRVO or HRVO for no more than 4 months. Your eyesight and eye health will also be checked before you take part.

You must not have uncontrolled high blood pressure or any other eye-related problems. If you have other conditions or have previously received other treatments, 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, both men and 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?

This clinical trial is split into two parts. In Part 1, everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Faricimab as an injection into the study eye every four weeks for 20 weeks (a total of 6 injections)
- OR aflibercept as an injection into the study eye every four weeks for 20 weeks (a total of 6 injections)

You will have a 1 in 2 chance of being placed in either group.

In Part 2, you will receive faricimab treatment, even if you received aflibercept in Part 1. You will receive faricimab as an injection into the study eye every 4, 8, 12 or 16 weeks, depending on the condition of your eye. You will continue to have study visits every four weeks, but if faricimab injections are not scheduled at this time, you will have a “sham” treatment designed to feel like a real injection (an empty syringe without a needle will be pressed against your numbed eye instead).

Neither you nor your clinical trial doctor can choose or know the group you are in during Part 1 or how often you receive faricimab treatment during Part 2. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

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

In Part 1 of this clinical trial, you will be given the clinical trial treatment faricimab or aflibercept for 20 weeks. After this, in Part 2, you will be given faricimab for a further 48 weeks. 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.

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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/NCT04740931

Trial-identifier: NCT04740931

Inclusion Criteria:

- Foveal center-involved macular edema due to central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO), diagnosed no longer than 4 months prior to the screening visit
- Best-corrected visual acuity (BCVA) of 73 to 19 letters, inclusive (20/40 to 20/400 approximate Snellen equivalent)
- Sufficiently clear ocular media and adequate pupillary dilatation to allow acquisition of good quality retinal images to confirm diagnosis
- For women of childbearing potential: agreement to remain abstinent or use contraception, and agreement to refrain from donating eggs during the treatment period and for 3 months after the final dose of study treatment

Exclusion Criteria:

- Any major illness or major surgical procedure within 1 month before screening
- Uncontrolled blood pressure
- Stroke (cerebral vascular accident) or myocardial infarction within 6 months prior to Day 1
- Pregnant or breastfeeding, or intending to become pregnant during the study

Ocular Exclusion Criteria for Study Eye:

- History of previous episodes of macular edema due to RVO or persistent macular edema due to RVO diagnosed more than 4 months before screening
- Any current ocular condition which, in the opinion of the investigator, is currently causing or could be expected to contribute to irreversible vision loss due to a cause other than macular edema due to RVO in the study eye (e.g., ischemic maculopathy, Irvine-Gass syndrome, foveal atrophy, foveal fibrosis, pigment abnormalities, dense subfoveal hard exudates, or other non-retinal conditions)
- Macular laser (focal/grid) in the study eye at any time prior to Day 1
- Panretinal photocoagulation in the study eye within 3 months prior to Day 1 or anticipated within 3 months of study start on Day 1
- Any prior or current treatment for macular edema; macular neovascularization, including diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD); and vitreomacular-interface abnormalities, including, but not restricted to, IVT treatment with anti-VEGF, steroids, tissue plasminogen activator, ocriplasmin, C3F8, air or periocular injection
- Any prior intervention with verteporfin photodynamic therapy, diode laser, transpupillary thermotherapy, or vitreo-retinal surgery including sheathotomy

- Any prior steroid implant use including dexamethasone intravitreal implant (Ozurdex) and fluocinolone acetonide intravitreal implant (Iluvien)

Ocular Exclusion Criteria for Both Eyes:

- Prior IVT administration of faricimab in either eye
- History of idiopathic or autoimmune-associated uveitis in either eye
- Active periocular, ocular or intraocular inflammation or infection (including suspected) in either eye on Day 1