ForPatients
by Roche

Polypoidal Choroidal Vasculopathy (PCV)

A Phase IIIb/IV, multicentre, open-label, single-arm study to investigate the efficacy and safety of faricimab (RO6867461) in patients with polypoidal choroidal vasculopathy

Trial Status	Trial Runs In	Trial Identifier
Recruiting	10 Countries	MR43808

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

Trial Summary:

A study evaluating the effectiveness and safety of faricimab (RO6867461) in participants with polypoidal choroidal vasculopathy

F. Hoffmann-La Roche Ltd
Sponsor

Phase 3/4
Phase

MR43808
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	50 years and above	No

Background and study aims:

Polypoidal choroidal vasculopathy (PCV) is a disease primarily affecting the blood vessels (choroidal vessels) under the light-sensitive membrane at the back of the eye (retina). This results in damage to the retina where the cells responsible for vision are present. Polypoidal injuries (lesions) commonly lead to significant subretinal bleeding (hemorrhage), often requiring aggressive therapy. Although the current treatment has demonstrated clinical benefit for patients with PCV, many limitations exist in understanding the disease. The burden of frequent injections, incomplete closure of polypoidal lesions, and the risk of the disease coming back (relapse) support the need to develop new therapeutic treatments. Faricimab is a new treatment recently approved for retinal diseases, including PCV, in the USA, the EU, Japan, UK, Switzerland, Singapore, Thailand, Australia and other jurisdictions. However, there is very limited information on faricimab for the management of PCV. The aim of this study is to evaluate the effects,

good or bad, of long-term use of faricimab in participants with PCV, and to determine how safe faricimab is when given to participants with PCV.

Who can participate?

People who are over 50 years of age and have a confirmed diagnosis of macular PCV.

What does the study involve?

Participants may have to be a part of this study for about 2 years. The study will include:

1. Screening period: The screening period will last up to 28 days before the study starts. All participants will be screened to make sure they are a good fit for the study before the study begins.

2. Treatment period: This will consist of three periods: a treatment initiation period (Day 1-Week 12), an individualized constant treatment interval period (Week 20-Weeks 44 or 48), and a personalized treatment interval (PTI) period (Weeks 44 or 48-Week 104). Participants will first receive four injections of faricimab 6 mg, injection in the study eye (intravitreal [IVT]) every 4 weeks. Thereafter participants will receive faricimab 6 mg injections into the study eye at a variable intervals, between every 4, 8, 12, 16, or 20 weeks, depending on the condition of the study eye.

Participants will have to visit the clinic about every 4 weeks during the study.

3. Follow-up period: Participants will have a check-up 4-5 weeks after the last dose of faricimab. Those who complete the treatment period of 104 weeks will be followed up at Week 108 for monitoring of side effects.

What are the possible benefits and risks of participating?

Participants may or may not receive any benefit from participating in this study, but the information learned in this study may help patients with similar conditions in the future. Participants may experience side effects from the study drug, and these can be mild to severe and can vary from person to person. As faricimab has had limited testing in humans, not all side effects are known at this time. The known side effects related to the study drug are listed below:

Common side effects:

1. Bleeding of the mucous membrane covering the white of the eye and inner lid (conjunctival hemorrhage)

2. Moving spots or dark shapes in the vision (vitreous floaters)

3. Temporary increase in fluid pressure inside the eye (increase in intraocular pressure)

4. Eye pain

5. The supporting membrane under the retina detaches and develops a hole, which can result in a reduction of vision (retinal pigment epithelium tear)

Uncommon side effects:

1. Eye irritation, discomfort, or itching

2. Increased production of tears

3. Bleeding into the jelly-like filling of the eye (vitreous hemorrhage)

4. Scratched cornea, damage to the clear layer of the eyeball that covers the iris (corneal abrasion)

5. Eye redness

6. Blurred vision

7. Inflammation of the gel-like substance inside the eye (vitritis)

8. Inflammation in the iris and its adjacent tissue in the eye (iritis, iridocyclitis, uveitis)

9. Foreign body sensation in the eye

10. Serious inflammation or infection inside the eye (endophthalmitis)

11. Temporary decrease in vision

12. Tearing of the retina

Rare side effects:

1. Separation of the retina from the underlying pigment cell layer (retinal detachment)

Potential risks associated with the study drug are listed below:

Potential systemic (non-ocular) side effects of faricimab:

1. Sickness caused by blood clots in the blood vessels (arteries) (arterial thromboembolic events) such as sudden interruption of blood flow in the brain which can cause paralysis

and unconsciousness (strokes) and heart attack (myocardial infarctions) have been seen at a low rate in clinical trials with faricimab, and with anti-vascular endothelial growth factor eye drugs such as EYLEA (aflibercept) and LUCENTIS (ranibizumab).

Potential ocular side effects of faricimab:

1. As with all therapeutic proteins, there is the potential for a response of the immune system to the treatment with faricimab, which may show up as severe inflammation inside the eye.

2. As with all injections into the eye, there is a risk of developing traumatic clouding of the lens (cataract). This occurs when the injection needle directly injures the lens.

Risks associated with a few of the study procedures are listed below:

1. Injection into the eye: some participants develop increased pressure within the eye when a medication is injected into the eye. Participants with a history of damage to the nerve in the eye which is usually caused by high pressure in the eye (glaucoma) must be well-controlled on medication in order to participate in this study. While rare, some participants receiving injections of medication into their eye have developed infections inside and/or outside the eye (endophthalmitis and/or periocular infections), retinal detachment or cloudiness of the eye lens. Participants may experience blurred vision for a period of time after the injection itself.

2. Anesthetic procedure: participants may experience blurred vision, pain, or stinging in eye, watery eyes and redness, light sensitivity for a period after the numbing medication (anesthetic) is administered.

3. Indocyanin green angiography: indocyanin green is a dye needed for the procedure of indocyanin green angiography. Participants may experience discomfort at the needle site, and the injection of the dye could irritate the vein or cause redness or swelling at the injection site. The most common side effects of the dye are nausea and vomiting, and occasionally allergic reactions or feeling faint.

4. Fluorescein angiography: fluorescein is a dye needed for the procedure of fluorescein angiography Participants may experience discomfort at the needle site, and the injection of the dye could irritate the vein or cause redness or swelling at the injection site. The most common side effects of the dye are nausea and vomiting, and occasionally allergic reactions or feeling faint. The dye may also stain the skin and urine, although this will only last for about 1 day.

5. Eye drops: participants may experience blurred vision for a period of time after the eye drops used to dilate the pupil(s) for the various eye tests are administered. Participants should not drive or use machinery until this has resolved.

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Women who are pregnant, become pregnant, or who are currently breastfeeding, cannot take part in this study.

Where is the study run from?

F. Hoffmann-La Roche

Who is funding the study?

F. Hoffmann-La Roche

Who is the main contact?

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