ForPatients
by Roche

Choroidal neovascularizationMyopia

A clinical trial to look at how safe and well faricimab works compared with ranibizumab in people with choroidal neovascularization secondary to pathologic myopia

A Study to Evaluate the Efficacy and Safety of Faricimab in Patients With Choroidal Neovascularization Secondary to Pathologic Myopia

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	11 Countries	NCT06176352 2023-506707-25-00 CR44829

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 Choroidal Neovascularization Secondary to Pathologic Myopia

Trial Summary:

This is a Phase III, multicenter, randomized, double-masked, active comparator-controlled study evaluating the efficacy and safety of faricimab in patients with myopic choroidal neovascularization (CNV). This non-inferiority study will compare 6.0 mg faricimab versus 0.5 mg ranibizumab administered at a pro-re-nata (PRN) dosing regimen after an initial active IVT treatment administration at randomization (Day 1).

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT06176352 2023-506707-25-00 CR44829
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is the Poyang clinical trial needed?

Myopia, commonly known as short-sightedness, is caused by a larger or longer-shaped eyeball. In pathologic myopia, the walls of the eyeball can become extremely stretched and thin. The thinning in the back of the eye causes damage in the deeper layers under the retina, a layer of cells in the back of the eye that send signals to the brain. People with pathologic myopia are at risk of an eye condition called choroidal neovascularisation secondary to pathologic myopia (mCNV). In mCNV, vision loss is caused by the abnormal growth of new, leaky blood vessels at the back of the eye.

Current treatment of mCNV is with anti-vascular endothelial growth factor (anti-VEGF) therapies, such as ranibizumab. Anti VEGF medicines are given as an injection into the eye, also known as intravitreal (IVT) injections, but frequent treatments may be required and not everyone responds to treatment. Faricimab is designed to block growth of abnormal blood vessels and the leakage of fluid from them. Faricimab is approved by health authorities to treat adults with eye diseases such as diabetic macular oedema and neovascular age-related macular degeneration. Faricimab is now being investigated as treatment for mCNV. This clinical trial aims to compare the effects, good or bad, of faricimab versus ranibizumab in people with mCNV.

2. How does the Poyang clinical trial work?

This clinical trial is recruiting people with mCNV. People can take part if they have not yet been given any treatment for mCNV. People who take part in this clinical trial (participants) will be given either faricimab or ranibizumab at the start of the trial on Day 1, and then as needed for about 11 months. The clinical trial doctor will see the participants on a monthly basis. These hospital visits will include checks to see how the participant responds to the treatment and any side effects they may have. The total time of participation in the clinical trial will be about 1 year. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Poyang clinical trial?

The main clinical trial endpoint (the main results measured in the trial to see if the drug has worked) is the change from the start of treatment (baseline) in eyesight when using corrective lenses, known as ‘best-corrected visual acuity’ (BCVA), measured using an eye chart over Weeks 4, 8, and 12.

The other clinical trial endpoints include:

- The number of participants whose BCVA improves, stays the same or gets worse
- The number of participants who receive only 1 treatment injection by Weeks 12, 24 and 48
- The number of IVT injections participants receive by Weeks 12, 24 and 48
- The change in thickness of the eye layers at Weeks 4, 8, 12, and over time
- The change in the amount of fluid or damage to the layers beneath the retina

- The number and seriousness of side effects
- How faricimab affects the immune system

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old with fluid in the layers beneath the retina (known as ‘active’ mCNV) and are otherwise healthy. People may not be able to take part in this trial if their eye condition is not caused by pathologic myopia, or they have another eye condition affecting their vision. People may also not take part if they regularly take some medicines, have any major illness or surgery within 1 month of having tests to see if they can join the trial, have had cancer in the last year, have certain medical conditions (such as infection or uncontrolled blood pressure), are pregnant or breastfeeding, or are planning on becoming pregnant during the trial or within 3 months of finishing treatment.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be placed into one of two groups randomly (like flipping a coin) and given either:

- Faricimab, as an IVT injection once every month, as needed, for up to 11 months, or
- Ranibizumab, as an IVT injection once every month, as needed, for up to 11 months

Participants will have an equal chance of being placed in either group. This is a double-masked trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This helps to prevent bias and expectations about what will happen. However, the participant’s clinical trial doctor can find out which group the participant is in, if their safety is at risk. If treatment with faricimab or ranibizumab is not needed at a visit, a simulated (false) treatment procedure called ‘sham’ will be given. A sham procedure is designed to feel like a real injection, but instead, an empty syringe without a needle will be pressed against the numbed (anaesthetised) eye. This makes sure the trial treatment remains ‘masked’ to the participant.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment (faricimab) may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs or procedures in this clinical trial. Side effects can be mild to severe, even life or sight-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

Faricimab and ranibizumab Participants will be told about the known side effects of faricimab and ranibizumab and possible side effects based on human studies or knowledge of similar drugs. Faricimab and ranibizumab will be given as IVT injections. Participants will be told about any known side effects of IVT injections.

Potential benefits associated with the clinical trial Participants' vision may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

Inclusion Criteria:

- Treatment-naïve choroidal neovascularization (CNV) secondary to myopia
- Diagnosis of active myopic CNV in the study eye:
- Presence of high myopia, worse than -6 diopters of spherical equivalence
- Antero-posterior elongation measurement greater than or equal to 26.0 mm
- Presence of posterior changes compatible with pathologic myopia (e.g., tessellated fundus, lacquer cracks, etc.)
- Presence of active leakage from CNV on FFA (determined by Central Reading Centre [CRC])
- Presence of intraretinal or subretinal fluid or increase of CST on OCT (determined by CRC)
- BCVA of 78 to 24 letters, inclusive (20/32 to 20/320 approximate Snellen equivalent), using the Early Treatment Diabetic Retinopathy Study (ETDRS) protocol on Day 1
- Overtly healthy as determined by medical evaluation that includes medical history, physical examination, and laboratory tests
- Ability to comply with the study protocol, in the Investigator's judgment
- Other protocol-defined inclusion criteria apply

Exclusion Criteria:

- Any major illness or major surgical procedure within 1 month before screening
- Pregnancy or breastfeeding, or intention to become pregnant during the study or within 3 months after the final study treatment administration
- Uncontrolled blood pressure (systolic >180 millimetres of mercury [mmHg], diastolic >100 mmHg)
- Stroke (cerebral vascular accident) or myocardial infarction within 6 months prior to Day 1
- History of systemic or ocular disease that would contraindicate treatment with the investigational drug or comparator
- Uncontrolled glaucoma in study eye
- Any prior or concomitant treatment for CNV or vitreomacular-interface abnormalities, including, but not restricted to, intravitreal, periocular or laser interventions in study eye
- Prior or concomitant periocular or intravitreal pharmacological treatment, including anti-VEGF medication, for other retinal diseases (e.g. geography atrophy, nAMD, DME etc.) in study eye
- Other protocol-defined exclusion criteria apply