ForPatients
by Roche

Wet Age-Related Macular Degeneration

A clinical trial to compare faricimab with aflibercept in people with neovascular age-related macular degeneration. (Lucerne)

A Study to Evaluate the Efficacy and Safety of Faricimab in Participants With Neovascular Age-Related Macular Degeneration (LUCERNE)

Trial Status	Trial Runs In	Trial Identifier
Completed	21 Countries	NCT03823300 2018-004042-42 GR40844

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 Neovascular Age-Related Macular Degeneration (LUCERNE)

Trial Summary:

This study will evaluate the efficacy, safety, durability, and pharmacokinetics of faricimab administered at intervals as specified in the protocol, compared with aflibercept once every 8 weeks (Q8W), in participants with neovascular age-related macular degeneration (nAMD).

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

NCT03823300 2018-004042-42 GR40844
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

How does the LUCERNE clinical trial work? This clinical trial is recruiting people who have a type of eye disease called neovascular age-related macular degeneration, or nAMD.

© 2022 F. Hoffmann-La Roche Ltd

The purpose of this clinical trial is to compare the effects, good or bad, of faricimab versus aflibercept in patients with nAMD. In this clinical trial, you will get either faricimab or aflibercept as treatment.

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 nAMD.

If you have previously been treated for nAMD in the study eye or been given faricimab in either eye, have uncontrolled blood pressure or other eye related problems, you will not be able to join the trial.

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?
Everyone who joins this clinical trial will be split into 1 of 2 groups randomly (like flipping a coin) and given either:

- faricimab, given as an injection into your eye (the time between injections will be based on how your disease responds to the treatment and will vary throughout the trial)
- OR aflibercept, given as an injection into your eye every 4 weeks for the first 3 months, and then every 8 weeks until the end of the trial

You will have an equal chance of being placed in any group. Only one eye will be treated during the study. If you have nAMD in both eyes, the eye that has the worst vision will be treated with the clinical trial drug and you will be given the current standard treatment for your other eye.

© 2022 F. Hoffmann-La Roche Ltd

Neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk. You will have to see the clinical trial doctor every 4 weeks. As the times between treatments are different for each group, you will have to have a sham treatment during the visits where you do not need your treatment to make sure that nobody knows which group you are in.

How often will I be seen in follow-up appointments, and for how long?
You will be given the clinical trial treatment faricimab OR aflibercept for just over 2 years (108 weeks). You are free to stop this treatment at any time. After being given your last treatment, you will be seen once more by the clinical trial doctor after 4 weeks. This hospital visit will include checks to see how you are responding to the treatment and monitor 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.

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

Trial-identifier: NCT03823300

Inclusion Criteria:

- Treatment-naïve choroidal neovascularization (CNV) secondary to age-related macular degeneration (nAMD) in the study eye
- Ability to comply with the study protocol, in the investigator's judgment
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use acceptable contraceptive measures that result in failure rate <1% per year during the treatment period and for at least 3 months after the final dose of study treatment
- Other protocol-specified inclusion criteria may apply

Exclusion Criteria:

- Uncontrolled blood pressure, defined as systolic blood pressure >180 millimeters of mercury (mmHg) and/or diastolic blood pressure >100 mmHg while a patient is at rest on Day 1
- Pregnancy or breastfeeding, or intention to become pregnant during the study
- CNV due to causes other than AMD in the study eye
- Any history of macular pathology unrelated to AMD affecting vision or contributing to the presence of intraretinal or subretinal fluid in the study eye
- Any concurrent intraocular condition in the study eye that, in the opinion of the investigator, could either reduce the potential for visual improvement or require medical or surgical intervention during the study
- Uncontrolled glaucoma in the study eye
- Any prior or concomitant treatment for CNV or vitreomacular-interface abnormalities in the study eye
- Prior IVT administration of faricimab in either eye

© 2022 F. Hoffmann-La Roche Ltd

- History of idiopathic or autoimmune-associated uveitis in either eye
- Active ocular inflammation or suspected or active ocular or periocular infection in either eye
- Other protocol-specified exclusion criteria may apply

© 2022 F. Hoffmann-La Roche Ltd