ForPatients
by Roche

Age-Related Macular Degeneration

A study to evaluate the long-term safety and tolerability of faricimab administered in patients previously enrolled in Roche-sponsored studies

An open-label, multicenter extension study to evaluate the long-term safety and tolerability of faricimab administered in patients previously enrolled in studies sponsored by F. Hoffmann-La Roche Ltd

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Countries	YR42837

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

Trial Summary:

The purpose of this study is to assess long-term safety of faricimab therapy and provide access to continued treatment with faricimab, as applicable, to patients with Diabetic Macular Edema (DME), Neovascular Age-related Macular Degeneration (nAMD), or Retinal Vein Occlusion (RVO).

Faricimab is an experimental drug, which means health authorities have not approved it for the treatment of DME, nAMD, or RVO outside of a clinical study. As of November 2020, more than 3,350 patients have been enrolled in either the completed or ongoing clinical studies of faricimab in patients with DME and nAMD. Of these patients, more than 2,100 patients have received at least one dose of faricimab.

F. Hoffmann-La Roche Ltd (Switzerland), Genentech Inc (USA)
Sponsor

YR42837
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
Both	Mixed	No

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Who can participate?
Patients who were previously enrolled in the mainland of China and completed any of Roche-sponsored faricimab parent trials

What does the study involve?
Participants will be placed in a single treatment group:

Participants will receive faricimab 6 mg injections into the study eye at a variable interval depending on the condition of their eye. Frequency of injections will be determined by the study doctor, usually varying between every 4 weeks and every 16 weeks.

Participants will only be required to attend the clinic according to the study doctor's discretion, but the interval between visits should be no more than 4 months and no less than 21 days.

What are the possible benefits and risks of participating?
Your health may or may not improve in this study, but the information that is learned may help other people who have a similar medical condition in the future.

You may have side effects from the drugs or procedures used in this study. Side effects can be mild to severe and even life threatening, and they can vary from person to person. There may be a risk in exposing an unborn child to the study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to the study drug.

Where is the study run from?
Shanghai General Hospital (China)

When is the study starting and how long is it expected to run for?
August 2020 to August 2025

Who is funding the study?
F. Hoffmann-La Roche Ltd (Switzerland)
Genentech Inc (USA)