ForPatients
by Roche

Edema Macular Diabético

Estudo clínico para comparar faricimabe com aflibercepte em pessoas com edema macular diabético (RHINE)

RHINE: Um estudo fase III, multicêntrico, randomizado, duplo-mascarado, controlado por comparador ativo para avaliar a eficácia e segurança de RO6867461 em pacientes com Edema # Macular Diabético

Trial Status	Trial Runs In	Trial Identifier
Concluído	24 Countries	NCT03622593 2017-005105-12 GR40398

As informações abaixo foram obtidas diretamente de sites de registro público, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com etc., e não foram editadas.

Official Title:

Um estudo fase III, multicêntrico, randomizado, duplo-mascarado, controlado por comparador ativo para avaliar a eficácia e segurança de RO6867461 em pacientes com edema macular diabético

Trial Summary:

Trata-se de um estudo de Fase III, duplo-mascarado, multicêntrico, randomizado, controlado por comparador ativo, de grupos paralelos, avaliando a eficácia, a segurança, a farmacocinética e a frequência ideal de tratamento de RO6867461 administrado por injeção intravítrea (IVT) em intervalos de 8 semanas ou PTI de aproximadamente 100 semanas de duração (excluindo o período de triagem) a pacientes com EMD.

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Roche	Fase 3
Sponsor	Phase

NCT03622593 2017-005105-12 GR40398
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

How does the RHINE clinical trial work?
This clinical trial is recruiting people who have a type of disease called diabetic macular edema or DME.

The purpose of this clinical trial is to compare the effects, good or bad, of faricimab versus aflibercept in patients with DME. 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 diabetic macular edema. You must also be taking regular treatment for your diabetes.

If you have previously 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 3 groups randomly and given either:

- faricimab, given as an injection into your eye every 8 weeks

- OR 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 8 weeks

You will have a one in three chance of being placed in any group. Only one eye will be treated during the study. If you have DME 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.

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. 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 under 2 years (96 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 https://clinicaltrials.gov/ct2/show/NCT03622593

Trial-identifier: NCT03622593