

# ForPatients

by Roche

zakrzep #y#y #rodkowej siatkówkiNiedro#no## #y# siatkówkiZakrzep obejmuj#cy po#ow#  
siatkówkibrz#k plamki #ó#tej

**Wieloo#rodkowe, randomizowane, podwójnie maskowane badanie fazy III kontrolowane porównawcz# substancj# czynn# w celu oceny skuteczno#ci i bezpiecze#stwa stosowania faricimabu u pacjentów z obrz#kiem plamki wtórnym do zakrzepu #y#y #rodkowej siatkówki lub zakrzepu obejmuj#cego po#ow# siatkówki**

**Trial Status**  
Zako#czone

**Trial Runs In**  
22 Countries

**Trial Identifier**  
NCT04740931 2020-000441-13  
GR41986

Informacje pochodz# bezpo#rednio ze stron internetowych rejestrów publicznych, takich jak ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com itp. i nie by#y edytowane.

## Official Title:

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## Trial Summary:

**F. Hoffmann-La Roche Ltd**  
Sponsor

**Badanie fazy III**  
Phase

**NCT04740931 2020-000441-13 GR41986**  
Trial Identifiers

## Eligibility Criteria:

**Gender**  
All

**Age**  
#18 Years

**Healthy Volunteers**  
No

## How does the COMINO clinical trial work?

This clinical trial is recruiting people who have macular oedema (swelling within the macula part of the eye) that is caused by central retinal vein occlusion (CRVO) or hemiretinal vein occlusion (HRVO). CRVO means that all of the branches of the central

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retinal vein in the eye have become blocked and HRVO means that half of the branches of the central retinal vein have become blocked. CRVO and HRVO can cause fluid to leak into the macula. This build-up of fluid causes swelling that can affect vision.

The purpose of this clinical trial is to compare the effects, good or bad, of faricimab against aflibercept in patients with macular oedema due to CRVO or HRVO. If you take part in this clinical trial, you will receive either faricimab or aflibercept for the first 20 weeks, followed by faricimab for a further 48 weeks.

Faricimab blocks the two important pathways that are thought to be involved in CRVO and HRVO: vascular endothelial growth factor (VEGF) and angiopoietin-2 (Ang-2). Aflibercept blocks VEGF only.

## **How do I take part in this clinical trial?**

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with macular oedema due to CRVO or HRVO for no more than 4 months. Your eyesight and eye health will also be checked before you take part.

You must not have uncontrolled high blood pressure or any other eye-related problems. If you have other conditions or have previously received other treatments, you may not be able to take part.

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.

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## **What treatment will I be given if I join this clinical trial?**

This clinical trial is split into two parts. In Part 1, everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Faricimab as an injection into the study eye every four weeks for 20 weeks (a total of 6 injections)
- OR aflibercept as an injection into the study eye every four weeks for 20 weeks (a total of 6 injections)

You will have a 1 in 2 chance of being placed in either group.

In Part 2, you will receive faricimab treatment, even if you received aflibercept in Part 1. You will receive faricimab as an injection into the study eye every 4, 8, 12 or 16 weeks, depending on the condition of your eye. You will continue to have study visits every four weeks, but if faricimab injections are not scheduled at this time, you will have a “sham” treatment designed to feel like a real injection (an empty syringe without a needle will be pressed against your numbed eye instead).

Neither you nor your clinical trial doctor can choose or know the group you are in during Part 1 or how often you receive faricimab treatment during Part 2. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

## **How often will I be seen in follow-up appointments and for how long?**

In Part 1 of this clinical trial, you will be given the clinical trial treatment faricimab or aflibercept for 20 weeks. After this, in Part 2, you will be given faricimab for a further 48 weeks. You are free to stop this treatment at any time.

While being given treatment, you will still be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and to 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.

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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/NCT04740931>

Trial-identifier: NCT04740931

## ***Inclusion Criteria:***

- Podpisanie formularza #wiadomej zgody
- Wiek #18 lat w momencie podpisywania formularza #wiadomej zgody
- Obrz#k plamki z zaj#ciem do#ka #rodkowego, spowodowany przez BRVO, z rozpoznaniem nie wcze#niej ni# 4 miesi#ce przed wizyt# przesiewow#, potwierdzony przez centralny o#rodek Obrz#k plamki z zaj#ciem do#ka #rodkowego, spowodowany przez CRVO lub HRVO, z rozpoznaniem nie wcze#niej ni# 4 miesi#ce przed wizyt# przesiewow#, potwierdzony przez centralny o#rodek bada# obrazowych (CRC) na podstawie obrazowania SD-OCT (lub SS-OCT)
- CRVO lub HRVO definiuje si# wed#ug wyst#powania krwotoku siatkówkowego, poszerzenia #o#yska w#o#niczkowego, poszerzenia uk#adu #ylnego lub innych cech biomikroskopijnych zakrzepu #y#y siatkówki (RVO; neowaskularyzacja, krwawienie do cia#a szklatego) w ca#ej siatkówce (CRVO) lub w dwóch kwadrantach siatkówki (HRVO)
- BCVA 73 do 19 liter w##cznie (odpowiada ok. 20/40 do 20/400 na tablicy Snellena) w ocenie przy pomocy tablicy ETDRS do badania ostro#ci wzroku, przy wyj#ciowej odleg#osci badania wynosz#cej 4 metry (dodatkowe informacje przedstawiono w instrukcji dotycz#cej BCVA), w dniu 1
- CST #325  $\mu\text{m}$ , zmierzona w badaniu SD-OCT Spectralis, lub #315  $\mu\text{m}$ , zmierzona w badaniu SD-OCT Cirrus lub SD-OCT Topcon, w ocenie przesiewowej (dopuszcza si# SS-OCT po potwierdzeniu przez CRC)
- Wystarczaj#ca przezroczysto## o#rodków optycznych i odpowiednie rozszerzenie #renic, pozwalaj#ce na uzyskanie wysokiej jako#ci obrazów siatkówki w celu potwierdzenia rozpoznania

## ***Exclusion Criteria:***

- Wcze#niejsze epizody obrz#ku plamki spowodowanego RVO w wywiadzie lub utrzymuj#cy si# obrz#k plamki spowodowany RVO, rozpoznany wcze#niej ni# 3 miesi#ce przed ocen# przesiewow#
- Poprawa BCVA o #10 liter w ocenie przy pomocy tablicy ETDRS mi#dzy ocen# przesiewow# a dniem 1
- Jakakolwiek aktualnie wyst#puj#ca choroba oczu, która w opinii badacza powoduje obecnie lub mog#aby powodowa# w przysz#osci nieodwracaln# utrat# wzroku z przyczyn innych ni# obrz#k plamki wywo#any przez RVO w oku badanym (np. niedokrwienne zwyrodnienie plamki, zespół Irvine'a-Gassa, zanik do#ka #rodkowego, w#óknienie do#ka #rodkowego, zaburzenia pigmentacji, g#sty poddo#kowy wysi#k twardy lub inne stany niedotycz#ce siatkówki)
- Obecno## wp#ywaj#cego na wzrok krwotoku do cia#a szklatego w dniu 1
- Odwarstwienie siatkówki lub otwór w plamce (stadium 3 lub 4)
- Afakia lub wszczępienie soczewki wewn#trzga#kowej do komory przedniej oka

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- Dowolna operacja za#my lub leczenie powik#a# operacji za#my przy pomocy steroidów lub naci#cia torebki laserem YAG (granat itrowo-glinowy) w ci#gu 3 miesi#cy przed dniem 1w wywiadzie