ForPatients
by Roche

Paroxysmal nocturnal hemoglobinuria (PNH)

Badanie maj#ce na celu ocen# skuteczno#ci i bezpiecze#stwa stosowania krowalimabu w porównaniu z ekulizumabem u pacjentów doros#ych i nastoletnich z nocn# napadow# hemoglobinuri# (NNH) nieleczonych wcze#niej inhibitorami dope#niacza.

A Phase III Study Evaluating the Efficacy and Safety of Crovalimab Versus Eculizumab in Participants With Paroxysmal Nocturnal Hemoglobinuria (PNH) Not Previously Treated With Complement Inhibitors.

Trial Status	Trial Runs In	Trial Identifier
Aktywne, nie rekrutuje	23 Countries	NCT04434092 2019-004931-21 2023-506498-36-00 BO42162

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

NCT04434092 2019-004931-21 2023-506498-36-00 BO42162
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All		No

How does the COMMODORE 2 clinical trial work? This clinical trial is recruiting people who have paroxysmal nocturnal hemoglobinuria (PNH), a blood disorder that involves the breakdown of red blood cells. In order to take part, patients must not have had any previous treatment with a type of medicine called a complement inhibitor, such as eculizumab or ravulizumab.

The purpose of this clinical trial is to compare the effects, good or bad, of crovalimab against eculizumab in patients with PNH. If you take part in this clinical trial, you will receive either crovalimab or eculizumab.

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 PNH. You must not have had any previous treatment with a type of medicine called a complement inhibitor, and you will not be able to take part if you are pregnant or breastfeeding.

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.

Your doctor will conduct some 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 participating in the trial. You will also be told what other treatments are available so that you may decide if you still want to participate.

While taking part in the clinical trial, you will need to either not have heterosexual intercourse or use contraception for safety reasons.

What treatment will I be given if I join this clinical trial? This clinical trial is ‘open-label’, which means that you and your doctor will know what treatment you are receiving.

If you join this clinical trial, you will be entered into one of two groups:

- **Crovalimab group**: you will receive crovalimab, given as an infusion into the vein once on Day 1 of the trial, then as an injection under the skin (subcutaneous) every week for four weeks. After four weeks, crovalimab will be given as a subcutaneous injection once every four weeks for a total of 24 weeks.
- OR **eculizumab group**: you will receive eculizumab, given as an infusion into the vein once every week for four weeks, followed by once every two weeks for a total of 24 weeks.

Twice as many patients will be placed randomly in the crovalimab group than in the eculizumab group.

After receiving treatment for 24 weeks, you will have the opportunity to continue crovalimab treatment (crovalimab group) or switch to crovalimab (eculizumab group) if the clinical trial doctor thinks it is in your best interest.

How often will I be seen in follow-up appointments and for how long? You will be given either the clinical trial treatment crovalimab OR eculizumab for 24 weeks. After that, you may continue to receive crovalimab (if you were in the crovalimab group) or switch to crovalimab (if you were in the eculizumab group) if it is in your best interests. During the study, you will need to attend regular visits for treatments and other assessments to see how you are responding to the treatment and any side effects that you may be having, until you complete the study. You are free to stop treatment at any time.

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://www.clinicaltrials.gov/ct2/show/NCT04434092?recrs=b&cond=PNH&draw=2&rank=3

Trial-identifier: NCT004434092

Inclusion Criteria:

- Wiek #12 lat
- Masa cia#a #40 kg
- Udokumentowane rozpoznanie NNH
- Aktywno## LDH #2 x GGN w ramach bada# przesiewowych
- Szczepienie przeciwko Neisseria meningitidis w ci#gu <3 lat przed rozpocz#ciem badania

Exclusion Criteria:

- Otrzymywanie obecnie lub w przesz#o#ci leczenia inhibitorami uk#adu dope#niacza
- Liczba p#ytek krwi <30 000/mm3 podczas bada# przesiewowych
- ANC <500/mikrolitr podczas bada# przesiewowych
- Allogeniczny przeszczep szpiku kostnego
- Zaka#enie Neisseria meningitidis w ci#gu sze#ciu miesi#cy poprzedzaj#cych badania przesiewowe