ForPatients
by Roche

Atypical Hemolytic Uremic Syndrome (aHUS)

A clinical trial to look at how well crovalimab works in adults and adolescents with atypical hemolytic uremic syndrome (aHUS)

A Study Evaluating the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Crovalimab in Adult and Adolescent Participants With Atypical Hemolytic Uremic Syndrome (aHUS)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	19 Countries	NCT04861259 2020-002475-35,2023-505089-27-00 BO42353

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

Trial Summary:

This study aims to evaluate the efficacy and safety of crovalimab in adult and adolescent participants with aHUS.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04861259 2020-002475-35,2023-505089-27-00 BO42353
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=12 Years	No

1. HOW DOES THE BO42353 CLINICAL TRIAL WORK?

This clinical trial is recruiting adults and adolescents who have a particular type of disease called atypical hemolytic uremic syndrome (aHUS).

The purpose of this clinical trial is to test the effects of crovalimab in two different groups of patients, based on whether or not they have previously received a specific type of treatment for aHUS.

2. 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 aHUS. You must be at least 12 years of age and weigh at least 40 kilograms.

You must not have a history of kidney disease or any other condition, apart from aHUS, that causes your kidneys to not work as well as they should. You may not be able to take part in the study if you have been diagnosed with certain conditions in the past, if you previously received certain treatments, or if you are pregnant or breastfeeding.

If you think this clinical trial may be suitable for you, and you 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. The clinical trial doctor 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 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 these tests recently, they may not need to be repeated.

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.

If you are a woman and not currently pregnant but can become pregnant, you will need to either not have heterosexual intercourse or take contraceptive medication.

3. WHAT TREATMENT WILL I BE GIVEN IF I JOIN THIS CLINICAL TRIAL?

Everyone who joins this clinical trial will be given crovalimab. Your first treatment will be given as an infusion into a vein, followed by injections under the skin, as follows:

Week 1:

Day 1: Crovalimab as an injection into a vein (infusion)

Day 2: Crovalimab as an injection under the skin

Weeks 2–4:

Crovalimab as an injection under the skin once a week

Week 5 onwards:

Crovalimab as an injection under the skin every 4 weeks.

The first few doses (up to Week 5) will be given in the clinic or hospital. During these visits, doctors will show you and/or your caregiver how to administer the injections so that you can continue treatment outside of the clinic. However, you still have the option to come to the clinic to receive treatment, if you prefer.

4. HOW OFTEN WILL I BE SEEN IN FOLLOW-UP APPOINTMENTS AND FOR HOW LONG?

You will be given crovalimab for a minimum of 25 weeks, and you may continue longer if you and your clinical trial doctor determine that it is working well for you.

While you are receiving study treatment, you will be seen regularly by the clinical trial doctor (once a week initially, followed by every 2 weeks and then every 4 weeks). If you continue to take crovalimab after the first 24 weeks (6 months), the clinical trial doctor will continue to see you every 8 weeks until Week 49. Thereafter, he/she will see you every 16 weeks for as long as you remain in the study. These visits will include checks to see how you are responding to the treatment and any side effects that you may be having. Your study center may organize for some visits to be done in your home if you would like to, on Week 13, 21 and 33.

If crovalimab works well for you, it is intended to be a life-long treatment but you are free to stop this treatment at any time. If you received crovalimab treatment for at least 25 weeks and your disease improved, but you or your clinical trial doctor decide to stop treatment, you may be able to re-start treatment at a later date if your disease gets worse.

If you decide to stop treatment with crovalimab and switch to a different treatment (eculizumab or ravulizumab), your clinical trial doctor will ask to see you every 1–2 weeks for 10 weeks to check on any side effects you may have during this time. You will also be asked to return for a safety clinic visit after 6 months, and will receive a safety telephone call 11 months after your last dose of crovalimab to monitor your health.

5. 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/NCT04861259

Trial-identifier: NCT04861259