ForPatients
by Roche

Atypical Hemolytic Uremic Syndrome (aHUS)

A clinical trial to look at how safe and effective crovalimab is in children and adolescents with atypical haemolytic uraemic syndrome (aHUS)

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

Trial Status	Trial Runs In	Trial Identifier
Recruiting	14 Countries	NCT04958265 2020-002437-15 BO42354

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 pediatric participants with aHUS.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT04958265 2020-002437-15 BO42354
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=28 Days & <= 17 Years	No

1. HOW DOES THE COMMUTE-p (BO42354) CLINICAL TRIAL WORK?

This clinical trial is recruiting people who have a type of disease called atypical haemolytic uraemic syndrome (aHUS). In order to take part, you must be less than 18 years old and have been diagnosed with aHUS.

The purpose of this clinical trial is to test how safe and effective crovalimab is and to understand the way your body processes this medicine.

2. HOW DO I TAKE PART IN THIS CLINICAL TRIAL?

To be able to take part in this clinical trial, you must be less than 18 years old (infants must be at least 28 days old and weigh at least 5 kg). You must also be up to date with certain vaccinations in order to take part in this clinical trial.

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 must not have had any organ transplants (other than kidney) or have received dialysis treatment for more than four weeks. If you have certain other medical conditions or have received certain other treatments, you may also not be able to take part in this clinical trial.

If you and your caregiver 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. They will give you all the information you need to make your decision about taking part in this 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 these tests recently, they may not need to be repeated.

Before starting the clinical trial, you and your caregiver 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, female patients who could become pregnant will need to either not have heterosexual intercourse or take contraceptive medications for safety reasons.

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

Everyone who joins this clinical trial will be given crovalimab. Crovalimab treatment will be split into two parts: the loading dose series and the maintenance doses (for at least 24 weeks) but the doses and timings will vary depending on the individual patient’s weight.

In patients who weigh at least 12 kg, crovalimab will be given as an injection into the vein (infusion) on Day 1, and as an injection under the skin on Day 2 during Week 1 of the loading dose series. During Weeks 2, 3 and 4, crovalimab will be given as an injection under the skin once a week.

After this, for the maintenance doses (starting at Week 5), crovalimab will be given as an injection under the skin every two or four weeks (depending on the patient’s weight) until the end of the clinical trial.

In patients who weigh less than 12 kg, crovalimab will be given as an injection into the vein (infusion) on Day 1 and as an injection under the skin on Day 2 during Week 1 of the loading dose series.. Maintenance doses of crovalimab will then be given every two weeks as injections under the skin, from Week 3 onwards.

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

You will be given crovalimab for at least 24 weeks, and you may continue treatment for longer, if you and your doctor determine that it is working well for you. You are free to stop this treatment at any time. For the first 5 weeks of treatment, you will need to go to a hospital or clinic, so that your doctor can teach you and/or your caregiver how to give your injections. After this, you and/or your caregiver will have the option to give yourself your injections, if preferred. You will still be seen regularly by your doctor during and after treatment. During treatment, you will be seen regularly by your 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-week period, your doctor will continue to see you every 4 months. These clinical visits will include checks to see how you are responding to the treatment and if you are having any side effects.

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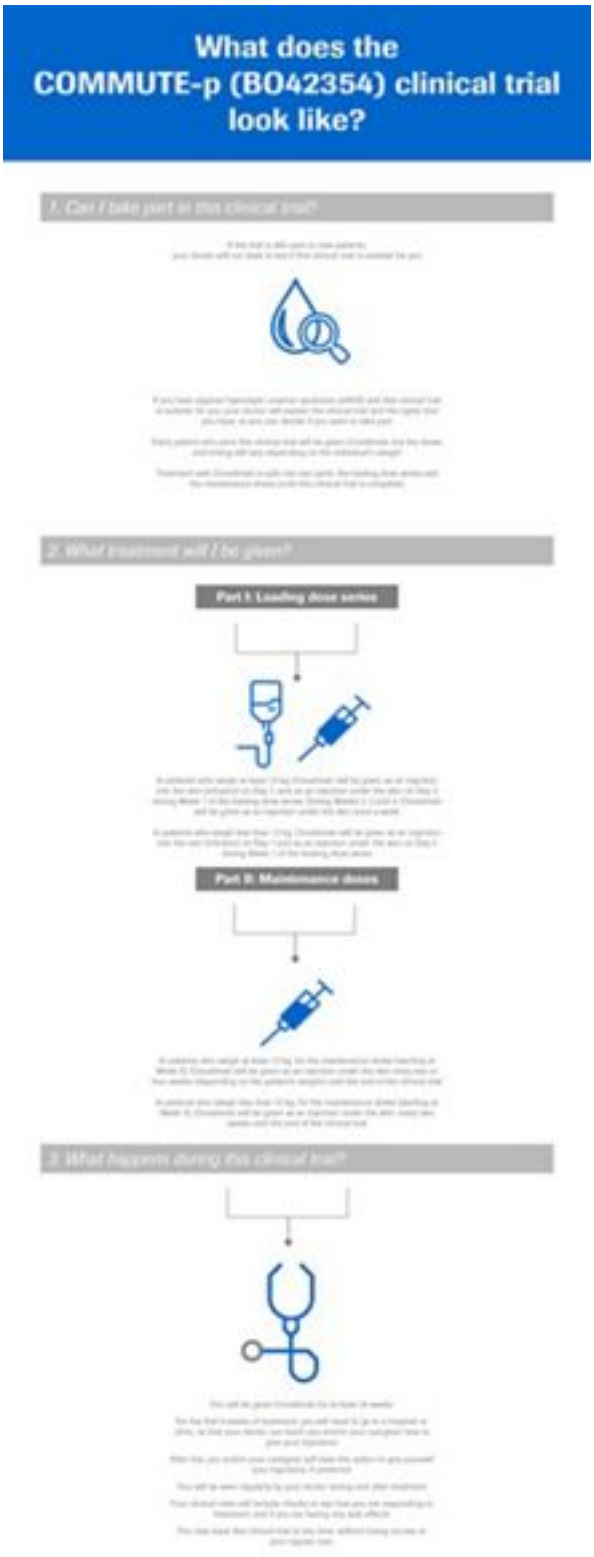

5. WHAT HAPPENS IF I AM UNABLE TO TAKE PART IN THIS CLINICAL TRIAL?

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 For Patient page or follow this link to ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT04958265

Trial-identifier: NCT04958265