ForPatients
by Roche

Sickle Cell Disease

A phase Ib randomized, placebo-controlled study evaluating the safety, pharmacokinetics, pharmacodynamics, and efficacy of crovalimab for the management of acute uncomplicated vaso-occlusive episodes in patients with sickle cell disease

A clinical trial to evaluate the safety and effectiveness of crovalimab for the treatment of pain crises, also called vaso-occlusive episodes (VOE), in people with sickle cell disease (SCD)

Trial Status	Trial Runs In	Trial Identifier
Completed	10 Countries	NCT04912869 2020-004840-27 BO42452

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase IB Randomized, Placebo-Controlled Study Evaluating the Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of Crovalimab for the Management of Acute Uncomplicated Vaso-Occlusive Episodes (VOE) in Patients With Sickle Cell Disease (SCD)

Trial Summary:

The purpose of this study is to evaluate crovalimab for the treatment of a sickle cell pain crisis (also known as a VOE) that requires hospitalisation in adult and adolescent participants with SCD. The primary objective of this study is safety and will additionally evaluate pharmacokinetics (how crovalimab is processed by your body), pharmacodynamics (how your body reacts to crovalimab) and the preliminary efficacy of crovalimab compared with placebo.

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Sponsor

Phase 1
Phase

NCT04912869 2020-004840-27 BO42452
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#12 Years & # 55 Years	No

1. HOW DOES THE CROSSWALK-a CLINICAL TRIAL WORK?

This clinical trial is recruiting people who have sickle cell disease (SCD) and are experiencing a pain attack (crisis) that requires admission to the hospital.

The purpose of this clinical trial is to look at the safety and effectiveness of crovalimab, and to understand the way your body processes (pharmacokinetics) and reacts (pharmacodynamics) to crovalimab.

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

You will be able to take part in this clinical trial if you:

- Have been diagnosed with a certain type of SCD (sickle cell anaemia or sickle cell beta zero thalassemia)
- Are currently experiencing a pain attack (crisis) that requires admission and treatment in the hospital
- Are between 12–55 years of age
- Are up to date with certain vaccinations

You will not be eligible to take part in this clinical trial if you:

- Have had more than 10 pain attacks (crises) requiring a medical visit within the last year
- Are experiencing pain that is not a SCD pain attack (crisis)
- Have an ongoing infection or have had a recent infection

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.

The clinical trial will begin when you have been admitted to the hospital for treatment of your pain attack (crisis). Your clinical trial doctor will ask you to confirm that you want to take part in the clinical trial and inform you of the risks and benefits. You will also be told what other treatments are available so that you may decide if you still want to take part.

You may 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.

For safety reasons while taking part in the clinical trial, women (who are not currently pregnant but can become pregnant) will need to agree to either use a reliable birth control method or not have heterosexual intercourse.

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

Everyone who joins this clinical trial will receive ONLY one dose of either:

- Crovalimab as a single infusion into the vein, OR
- Placebo as a single infusion into the vein

You will have a 2 in 3 (67%) chance of being in the crovalimab group and a 1 in 3 (33%) chance of being in the placebo group.

During the clinical trial, you can continue to have standard treatment for your pain attack (crisis) as recommended by your clinical trial doctor.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given a saline (salt water) infusion with no active ingredients (also known as a ‘placebo’). A placebo is used as a control, to make sure any health effects are from the clinical trial treatment rather than other factors.

Neither you nor your clinical trial doctor can choose or know the group you are in. An exception is made if your clinical trial doctor needs to know which group you are in for safety reasons.

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

While you are in hospital for treatment of your sickle cell pain attack (crisis), you will be seen by your clinical trial doctor.

After being given treatment with crovalimab or placebo, you will have regular tests and check-ups while you are hospitalised until you are well enough to go home from the hospital (discharged).

Once you are discharged from the hospital, you will have 5 telephone check-ups and 2 clinic visits with your clinical trial doctor to check on your health and any side effects you may be having.

The clinical trial will last for a total of 322 days (approximately 10.5 months) after you are given the clinical trial treatment (crovalimab or placebo).

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

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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

Trial-identifier: NCT04912869

Inclusion Criteria:

- Body weight >=40 kg.
- Confirmed diagnosis of HbSS (SCD genotype of sickle cell anemia) or HbS#0 (SCD genotype of sickle cell beta zero thalassemia).
- Vaccination against Neisseria Meningitidis serotypes A, C, W, and Y.
- Vaccinations against H. influenzae type B and S. pneumoniae.
- Participants vaccinated against SARS-CoV-2 are eligible, as long as it has been 3 days or more after inoculation with the vaccine.
- Diagnosis of an acute uncomplicated VOE, that requires admission to a hospital/acute medical facility and treatment with parenteral opioid analgesics.
- Adequate hepatic and renal function.
- Hemoglobin >=5 grams/deciliter (g/dL)
- Platelet count >=100,000/microliter (µL)
- Participants receiving SCD-directed therapies must be on a stable dose for >=28 days.
- For female participants of childbearing potential, an agreement to remain abstinent or use contraception for 322 days (approximately 10.5 months) after the dose of study treatment.

Exclusion Criteria:

- More than 10 VOEs within the last 12 months prior to presentation, that have required a medical facility visit.
- Pain related to the current VOE ongoing for >36 hours.
- Acute pain related to avascular necrosis, hepatic or splenic sequestration, or priapism.
- Pain atypical of an acute uncomplicated VOE.
- Evidence of or suspicion of ACS.
- Evidence or high suspicion of a severe systemic infection.
- Major surgery and/or hospitalization for any reason within 30 days.
- History of Neisseria meningitidis infection within 6 months prior.
- Known HIV infection with a documented CD4 count <200 cells/µL.
- Transfusion or receipt of blood products within 3 months or current participation in a chronic transfusion protocol.
- Immunized with a live attenuated vaccine within 30 days.
- History of hematopoietic stem cell transplant.
- Known or suspected hereditary complement deficiency.
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 322 days (approximately 10.5 months) after the study drug administration.
- Participation in another interventional treatment study with an investigational agent or use of any experimental therapy within the prior 28 days or within five half-lives of that investigational product, whichever was greater.