ForPatients
by Roche

Uveitic Macular Edema

A clinical trial to look at how well RO7200220 works to improve vision compared with a sham treatment in people with inflammation-related fluid swelling in the eye (uveitic macular edema), and how safe RO7200220 is at different doses

Vamikibart in Participants With Uveitic Macular Edema

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	19 Countries	NCT05642325 GR44278

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 III, Multicenter, Randomized, Double-Masked, Sham-Controlled Study to Investigate the Efficacy, Safety, Pharmacokinetics and Pharmacodynamics of Vamikibart Administered Intravitreally in Patients With Uveitic Macular Edema

Trial Summary:

This study will assess the efficacy and safety of vamikibart in participants with uveitic macular edema.

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

NCT05642325 GR44278
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is the Sandcat clinical trial needed?

Uveitic macular edema (UME, sometimes called ‘UMO’ or retinal swelling or cystoid edema) is a common complication of inflammation inside the eye (known as ‘uveitis’). UME is caused by a build-up of fluid in a delicate layer at the back of the eye, called the

retina, causing changes to vision and eye damage. Uveitis is less common in children and young people than in adults but can be more difficult to treat and have poorer outcomes. The main current treatment for UME is steroid medications which can work well at controlling inflammation and preventing fluid build-up. However, steroids can cause serious side effects affecting the eyes and general health, particularly in children, and their long-term use is not recommended. In this clinical trial, researchers are assessing if a non-steroid drug called RO7200220 will improve vision in children and adults with UME.

2. How does the Sandcat clinical trial work?

This clinical trial is recruiting people who have been diagnosed with uveitis and have developed UME, not caused by an infection (non-infectious uveitis). The purpose of this clinical trial is to compare the effects, good or bad, of RO7200220 treatment against a sham treatment (when no active treatment is given). People with UME, who take part in this clinical trial will receive either RO7200220 by injection into the eye, or the sham treatment. The sham treatment procedure feels like a real injection but does not involve a needle being inserted into the eye, and nothing is injected into the eye. Each participant will receive clinical trial treatment in one eye (‘study eye’). Participants will be given RO7200220 OR sham every 4 weeks for the first 12 weeks. After Week 12, participants will continue to be seen by the clinical trial doctor every 4 weeks. No treatment will be given at Week 16. Clinical trial treatment (RO7200220 OR sham) will be given as needed from Week 20 to Week 48. Trial participants will have a final study assessment at Week 52, and then will continue their usual care with their doctor. Overall, participants will have about 15 clinical trial visits, for a total time in the clinical trial of about one year. Hospital visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Sandcat clinical trial?

The main clinical trial result that is measured to assess if RO7200220 has worked is how many participants have an improvement of at least 15 letters in a vision test at 16 weeks – compared to the start of the trial. Other key clinical trial endpoints are evaluations of change from the start of the trial in vision and changes in the amount of retinal fluid swelling (UME).

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 2 years old and have been diagnosed with UME caused by non-infectious uveitis. For participants aged 2-17 years, agreement

(or consent) is required from both the participants and their caregiver/legal guardian to the clinical trial treatment and checks at sites that see young people. People may not be able to take part in this trial if they have certain other medical conditions including eye conditions that makes the trial unsuitable for them, are currently taking or have previously received certain treatments, are pregnant or breastfeeding, or are planning to become pregnant.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be split randomly into three groups (with an equal chance of receiving one of the three treatment schedules - a 1 in 3 chance of being placed in any group) and will receive either RO7200220 at a dose of 1.0mg or RO7200220 at a dose of 0.25mg or sham treatment. Participants will stay in the same treatment group and cannot switch groups during the trial. The clinical trial is split into two parts:

- **Part 1 (Day 1 to Week 12):** participants will receive either RO7200220 (Groups A and B) or sham (Group C) in the study eye every 4 weeks for a total of 4 treatments
- **Part 2 (Week 20 to Week 48):** participants will be given RO7200220 (Groups A and B) or sham (Group C) in the study eye if the trial doctor decides treatment is needed. From Week 4 onwards, the trial doctor may recommend that participants stop the clinical trial treatment if their vision or UME/uveitis gets worse and be given a different treatment for UME (called ‘rescue treatment’). Rescue treatment is any non#trial treatment, part of standard care; the type of treatment given will be decided by the trial doctor. If given rescue treatment, participants will not be given any further RO7200220 OR sham. Participants may continue to be seen by the clinical trial doctor every 4 weeks until the end of the trial, but they can also leave the trial at any time.

This is a double-masked trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over, to prevent bias and expectations about what will happen. However, the participant’s clinical trial doctor can find out which group the participant is in, if their safety is at risk.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision

to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual healthcare provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life-threatening and can vary from person to person. Existing information on the effectiveness and safety of RO7220200 from previous trials in people with retinal fluid swelling due to uveitis or diabetes will be available to trial doctors to help discuss the trial with potential participants. Potential participants will be told about the known side effects of the eye injection procedure, RO7220200 and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Since RO7220200 will be given as an injection into the study eye, the most common side#effects are those caused by the injection procedure itself.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT05642325

Inclusion Criteria:

- Female participants: Agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception as defined by the protocol
- Diagnosis of macular edema associated with non-infectious uveitis (NIU)
- Diagnosis of active or inactive, acute, or chronic NIU of any etiology and of any anatomical type (anterior, intermediate, posterior, panuveitis)
- BCVA letter score of 73 to 19 letters (inclusive) on Early Treatment Diabetic Retinopathy Study (EDTRS)-like charts

Exclusion Criteria:

- Evidence of active or latent syphilis infection
- Evidence of active or latent tuberculosis infection and/or positive tuberculosis assay, or previous or current HIV diagnosis
- Serious acute or chronic medical or psychiatric illness
- History of major ocular and non-ocular surgical procedures
- Uncontrolled IOP or glaucoma or chronic hypotony

- Any anatomical changes or media opacity in the study eye preventing evaluation of retina, vitreous, and capture of study images
- Prior use of IVT biologics including anti-VEGFs less than 2-4 months prior to Day 1; received IVT Methotrexate within 4 months prior to Day 1
- Prior macular laser therapy, cataract surgery within 6 months and laser capsulotomy within 3 months of Day 1
- Topical corticosteroids and/or topical NSAID > 3 drops per day in the 14 days prior to Day 1 (D1); intraocular or periocular corticosteroid injections in the 2 months prior to D1; subconjunctival corticosteroid injection within 1 month prior to Day 1; an OZURDEX implant in the 4 months prior to D1; YUTIQ, RETISERT or ILUVIEN implant in the 3 years prior to D1
- Diagnosis of macular edema due to any cause other than NIU
- Any major ocular conditions that may require medical or surgical intervention during the study period to prevent vision loss