ForPatients
by Roche

Myelin Oligodendrocyte Glycoprotein Antibody Disease (MOGAD)

A clinical trial to compare satralizumab with placebo, with or without background therapy, in people with myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Satralizumab in Patients With Myelin Oligodendrocyte Glycoprotein Antibody-Associated Disease

Trial Status	Trial Runs In	Trial Identifier
Recruiting	10 Countries	NCT05271409 2023-507196-22-00 WN43194

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, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab as monotherapy or in addition to baseline therapy in patients with myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)

Trial Summary:

The main objective of the study is to evaluate the efficacy of satralizumab compared with placebo based on time from randomization to the first occurrence of an adjudicated MOGAD relapse in the double-blind (DB) treatment period

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT05271409 2023-507196-22-00 WN43194
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#12 Years	No

1. Why is the Meteoroid clinical trial needed?

Meteoroid is a clinical trial designed to help people with a condition called myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD). In MOGAD, the immune system mistakenly attacks a protective covering around nerve fibres, making it hard for the brain to communicate with the rest of the body. Children and adults with MOGAD have attacks (known as 'relapses' after the first attack) that damage the nerves connecting the eyes to the brain (optic nerves), the spinal cord and/or the brain itself. This may cause eye pain and loss of vision, muscle weakness, loss of sensation, numbness and tingling, loss of bladder and/or bowel control, erectile dysfunction in men and other symptoms. While some symptoms may go away after an attack, some may only improve and then get worse with future relapses.

There is no approved, standard treatment for MOGAD. Medicines known as 'rescue therapy' can be given during an attack or relapse that act fast to dampen or weaken the immune system. Medicines can also be given to prevent relapses. However, these options do not always provide enough protection and can cause side effects. Safer and more convenient treatments that prevent MOGAD relapses are needed.

Satralizumab is a medicine that is approved in many countries for neuromyelitis optica spectrum disorder – another condition affecting the optic nerves and spinal cord. Health authorities have yet to approve satralizumab for treating MOGAD on its own (as monotherapy) or in combination with current therapy (also known as 'background therapy').

This clinical trial aims to compare the effects, good or bad, of satralizumab with placebo – a drug that contains no active ingredients, alone or in combination with background therapy in people with MOGAD.

2. How does the Meteoroid clinical trial work?

This clinical trial is recruiting people with MOGAD. People can take part if they have had at least one attack in the last year or at least two attacks in the last 2 years. People who join this clinical trial (participants) will be given the clinical trial treatment satralizumab OR placebo, either alone or with other background therapy. They will be treated until they have a relapse, or until researchers have seen a certain number of MOGAD relapses among the clinical trial participants. This could be up to 4 years. Participants may then be given satralizumab, either alone or with other background therapy, for up to a further 2 years. After about 6 months of treatment in the clinic, participants may have the option to have the treatment at home. The treatment can be given by themselves or by their caregiver, an adult family member, or a mobile nurse if available. The clinical trial doctor will see them regularly. These clinic visits will include checks to see how the participant responds to the treatment and any side effects they may have. Participants will visit the clinic within 1 month after the last dose of clinical trial treatment and again at 3 months (and 6 months for 12–17-year olds). They will also be contacted by telephone each month in between these clinic visits to check their health. The total time of participation in the clinical trial will be a

maximum of about 5 years. Participants can stop trial treatment and leave the clinical trial at any time.

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

The main clinical trial endpoint (the main result measured in the trial to see if the drug has worked and how safe it is) is the amount of time it takes for participants to have a MOGAD relapse after starting clinical trial treatment.

The other clinical trial endpoints include the:

- Number of relapses per year
- Number of changes in the nervous system (optic nerves, brain and spinal cord) per year, as measured on scans
- Number of participants that are given rescue therapy
- Number of participants per year that need to be treated in the hospital for at least 2 days
- Number of participants who do not relapse during the trial
- Change in memory and thinking during the trial (12–17-year olds only)
- Number and seriousness of side effects
- Change in weight, general health, heart function and risk of suicide
- Change in pain, eyesight, intensity of relapses, and any positive or negative effects that treatment has had on their health and wellbeing

4. Who can take part in this clinical trial?

People with MOGAD who meet certain criteria can take part in this trial. Participants must be at least 12 years old and weigh at least 20kg. People may not be able to take part in this trial if they have had a relapse within 3 months before starting the clinical trial unless they have fully recovered from this relapse, they are not able to have a magnetic resonance imaging (MRI) scan, they have certain other medical conditions or have previously taken certain medicines or are pregnant or breastfeeding.

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

Everyone will join 1 of 2 groups randomly (like flipping a coin) and be given either satralizumab or placebo, as an injection (under the skin of the belly or thigh) every 2 weeks in the first month then monthly, either alone or with other background therapy. Participants will have an equal chance of being placed in either group. This is a ‘double-blind’ part of the 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. This helps 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. This is also ‘placebo-controlled’. Comparing results with the placebo group helps the researchers know whether any changes seen result from the drug or occur by chance.

In the ‘open-label’ part of the trial, all participants will be given satralizumab as an injection (under the skin of the belly or thigh) every 2 weeks in the first month then every 4 weeks, either alone or with other background therapy. ‘Open-label’ means everyone involved, including the participant and the clinical trial doctor, will know the participant has been given satralizumab either alone or with other background therapy. Participants may also be given standard rescue therapy if they have a MOGAD attack during the trial.

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

Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate 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. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly.

Participants will be told about the known side effects of satralizumab and possible side effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known side effects of injections under the skin (subcutaneous injections).

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions in the future.

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: NCT05271409

Inclusion Criteria:

- Participants who are aged >=12 years at the time of signing Informed Consent Form
- Confirmed diagnosis of MOGAD with a history of >=1 MOGAD relapse in the 12 months prior to screening or >=2 attacks in the 24 months prior to screening
- Expanded Disability Status Scale (EDSS) score of 0-6.5 at screening

- Best corrected visual acuity (HCVA) better than 20/800 in each eye at screening
- Participants receiving either no or ongoing chronic immunosuppressant treatment (IST) for MOGAD at the time of screening
- For women of childbearing potential: participants who agree to remain abstinent or use adequate contraception during the treatment period and for at least 3 months after the final dose of satralizumab

Exclusion Criteria:

- Presence of aquaporin-4-antibodies (AQP4-IgG) in the serum
- History of anti-N-methyl-d-aspartate receptor (NMDAR) encephalitis
- Any concomitant disease other than MOGAD that may require treatment with ISTs or OCS or intravenous (IV) corticosteroids at doses >20 mg prednisone equivalent per day for >21 days during the study
- Participants who are pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final dose of satralizumab
- Participants with active or presence of recurrent bacterial, viral, fungal, mycobacterial infection, or other infection at baseline
- Participants with evidence of latent or active tuberculosis (excluding patients receiving chemoprophylaxis for latent tuberculosis infection)
- Participants with positive screening tests for hepatitis B and C
- Receipt of live or live attenuated vaccine within 6 weeks prior to baseline
- History of severe allergic reaction to a biologic agent