ForPatients
by Roche

Generalized Myasthenia Gravis (gMG) Myasthenia Gravis (IAB)

A clinical trial to look at how safe and effective satralizumab is at reducing certain signs of generalised myasthenia gravis (gMG)

A Study To Evaluate Efficacy, Safety, Pharmacokinetics, And Pharmacodynamics Of Satralizumab In Patients With Generalized Myasthenia Gravis

Trial Status	Trial Runs In	Trial Identifier
Recruiting	15 Countries	NCT04963270 WN42636

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 will evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of satralizumab compared with placebo in participants with generalized myasthenia gravis (gMG).

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

NCT04963270 WN42636
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=12 Years	No

How does the WN42636 clinical trial work?

This clinical trial is recruiting people who have a type of disease called myasthenia gravis (MG). In order to take part, patients must have MG that affects multiple muscle groups throughout the body (generalised MG [gMG]).

The purpose of this clinical trial is to understand the effects, good or bad, of satralizumab in combination with current treatment (background therapy) in patients with gMG. In this trial, you will receive either satralizumab in combination with background therapy or placebo in combination with background therapy.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 12 years old and have been diagnosed with gMG according to certain criteria.

You must not have been diagnosed with a type of MG that affects only the eyes (ocular MG) or had an operation to remove your thymus in the last 12 months. You must not have experienced a myasthenic crisis event (where the muscles that you use to breathe become weak) in the last three months. Certain types of vaccinations (live and attenuated [weakened] vaccines) are not allowed within six weeks before starting the clinical trial or during the clinical trial.

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.

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.

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.

While taking part in the clinical trial, and for at least three months after you have finished taking the clinical trial treatment, women (who are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial?

This clinical trial is split into two parts, called the double-blind period (Part 1) and the open-label period (Part 2).

In Part 1, everyone who joins this clinical trial will be split into two groups randomly (like flipping a coin) and given either:

- Satralizumab as an injection under the skin (subcutaneous) every four weeks for 24 weeks (plus an extra dose at Week 2) in addition to your current background gMG therapy

OR

- Placebo as an injection under the skin (subcutaneous) every four weeks for 24 weeks (plus an extra dose at Week 2) in addition to your current background gMG therapy

You will have an equal chance of being placed in either group.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

In Part 1, neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

If you complete Part 1 (double-blind period) of the clinical trial, you may enter Part 2 (open-label period). In Part 2, you will receive satralizumab every four weeks for between two to three and a half years.

During both Part 1 and Part 2, you will continue receiving your current background therapy for gMG at the same amount until at least Week 12 of Part 2. You should not change your background therapy unless this has been discussed with your clinical trial doctor.

How often will I be seen in follow-up appointments and for how long?

During Part 1 of the clinical trial, you will be given the clinical trial treatment satralizumab or placebo for 24 weeks. If you continue with Part 2 of the clinical trial, your total time in the clinical trial could be as long as four years.

After being given treatment, you will be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

You are free to stop this treatment at any time. After your final dose, your clinical trial doctor will follow up with you for a period of 12 weeks if you are an adult and 24 weeks if you are between 12 and 17 years old.

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 may 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.

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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/NCT04963270

Trial-identifier: NCT04963270