ForPatients
by Roche

Neuromyelitis optica spectrum disorder (NMOSD)

A clinical trial to look at how effective and safe satralizumab is for treating people with neuromyelitis optica spectrum disorder (NMOSD)

A Study In Neuromyelitis Optica Spectrum Disorder (NMOSD) With Satralizumab As An Intervention

Trial Status	Trial Runs In	Trial Identifier
Terminated	6 Countries	NCT05269667 MN42928

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

Objective of the trial is to describe the efficacy and safety of satralizumab in patients with aquaporin-4 (AQP4) antibody seropositive NMOSD, either treatment naive or inadequate responders to previous treatment with rituximab (RTX) (or its biosimilar)

Hoffmann-La Roche Sponsor	**Phase 4** Phase

NCT05269667 MN42928
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years & <= 74 Years	No

How does the SAKURABONSAI clinical trial work?

This clinical trial is recruiting people who have a type of disease called neuromyelitis optica spectrum disorder (NMOSD). In order to take part, patients must have been diagnosed with NMOSD according to specific criteria.

The purpose of this clinical trial is to test how effective and safe satralizumab is at treating patients with NMOSD, based on their previous treatment history. If you take part in this clinical trial, you will receive satralizumab.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be between 18 and 74 years old and have been diagnosed with NMOSD according to certain criteria (this will be confirmed with a test to look for specific antibodies in your blood). You must have either not had any previous treatment for NMOSD, or have had a poor response to previous treatment with rituximab within the last six months.

You must not be pregnant or breastfeeding, or intending to become pregnant within three months of your last dose of clinical trial treatment. If you have taken certain medications or have certain other medical conditions, you may not be able to take part in this 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. If you have had some of the tests recently, they may not need to be done again.

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, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or will need to use reliable contraception for safety reasons.

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

Everyone who joins this clinical trial will enter a screening period to make sure they are able to take part. Patients will then be split into two groups based on whether or not they have had previous treatment, but both groups will be given the same clinical trial treatment:

- Satralizumab as an injection under the skin (subcutaneous) at Weeks 0, 2 and 4, then every four weeks up to Week 92

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

You will be given the clinical trial treatment satralizumab for 92 weeks (roughly two years). You will have regular clinic visits during the treatment period (every two weeks until Week

4, then every four weeks until Week 12, then every 12 weeks after that). At some of these visits you will have assessments including blood tests, eye tests, MRI scans, spinal fluid sampling and questionnaires. You will also have a follow-up visit roughly 12 weeks after your last dose of clinical trial treatment. You are free to stop this treatment at any time.

The first dose of clinical trial treatment will be given at the clinic by a member of the clinical trial team during a scheduled visit. You will give yourself the next dose at Week 2 under the supervision of a clinical trial team member at the clinic. After you have had training from a healthcare provider, you will be able to give yourself the rest of your doses without supervision. You will be contacted by phone the next working day after every dose of satralizumab that you give to yourself so that the clinical trial team can check how you are feeling and discuss any side effects you may be having.

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 ForPatient page or follow this link to ClinicalTrials.gov

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