

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
Terminated

Trial Runs In
3 Countries

Trial Identifier
NCT05269667 MN42928

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:

SAkuraBonsai: Clinical, Imaging And Biomarker Open-Label Study In Neuromyelitis Optica Spectrum Disorder (NMOSD) With Satralizumab As An Intervention

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
All

Age
#18 Years & # 74 Years

Healthy Volunteers
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.

ForPatients

by Roche

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](https://clinicaltrials.gov)

Trial-identifier: NCT05269667

Inclusion Criteria:

- Age 18 to 74 years, inclusive, at the time of informed consent
- Have a diagnosis of AQP4 antibody seropositive NMOSD according to the International Panel for NMO Diagnosis (IPND) criteria
- For women of childbearing potential: agreement to either remain abstinent (refrain from heterosexual intercourse) or to use reliable means of contraception (physical barrier [patient or partner] in conjunction with a spermicidal product, contraceptive pill, patch, injectables, intrauterine device or intrauterine system) during the treatment period and for at least 3 months after the last dose of study drug Cohort 1 (treatment-naïve NMOSD patients)
- Confirmation of NMOSD diagnosis with AQP4+ antibodies
- Have clinical evidence of at least 1 documented attack or relapse (including first attack) in the last year prior to screening
- Naïve to maintenance therapy (disease-modifying therapy [DMT] or immunosuppressive therapy [IST]) Cohort 2 (NMOSD patients with inadequate response to RTX [or its biosimilar])
- Confirmation of NMOSD diagnosis and AQP4+ antibodies in the disease history of the patient
- Have a length of disease duration from first symptom of #5 years
- History of ongoing treatment with RTX (or its biosimilar) (at least 2 infusions) for NMOSD with a maximum duration of 6 months since last administration prior to enrolment in the study

- Ongoing disease activity after last RTX (or its biosimilar) infusion i.e., relapse and/or any new inflammatory event, confirmed by magnetic resonance imaging (MRI) or ophthalmological assessment

Exclusion Criteria:

Exclusion criteria Exclusion criteria for both the cohorts

- Inability to complete an MRI
- Participants who are pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final dose of satralizumab
- Any surgical procedure (except for minor surgeries) within 4 weeks prior to baseline
- Evidence of other demyelinating disease, including MS or progressive multifocal leukoencephalopathy (PML)
- Evidence of serious uncontrolled concomitant diseases that may preclude patient participation
- Active or presence of recurrent bacterial, viral, fungal, mycobacterial infection or other infection (excluding fungal infections of nail beds or caries dentium) at baseline
- Infection requiring hospitalization or treatment with intravenous (IV) anti-infective agents within 4 weeks prior to baseline visit
- Evidence of chronic active hepatitis B
- Evidence of active tuberculosis (TB)
- History or laboratory evidence of coagulation disorders
- Receipt of a live or live-attenuated vaccine within 6 weeks prior to baseline
- Presence or history of malignancy
- History of drug or alcohol abuse within 1 year prior to baseline
- History of diverticulitis that, in the Investigator's opinion, may lead to increased risk of complications such as lower gastrointestinal perforation
- History of severe allergic reaction to a biologic agent
- Active suicidal ideation within 6 months prior to screening, or history of suicide attempt within 3 years prior to screening
- Treatment with any investigational agent within 6 months prior to baseline or 5 drug elimination half-lives of the investigational agent (whichever is longer) Cohort 1 (treatment-naïve NMOSD patients)
- Any previous treatment with IL-6 inhibitory therapy (e.g., tocilizumab), alemtuzumab, total body irradiation, stem-cell therapy, or bone marrow transplantation
- Any previous treatment with eculizumab, belimumab, natalizumab, glatiramer acetate, fingolimod, teriflunomide, dimethyl fumarate, siponimod, or ozanimod
- Any previous treatment with anti-CD4, cladribine or mitoxantrone
- Any previous treatment with B-cell depleting agents
- Any previous treatment with immunosuppressants Cohort 2 (NMOSD patients with inadequate response to RTX)
- Discontinued RTX (or biosimilar) treatment due to any other reason than inadequate response to treatment