

Neuromyelitis optica spectrum disorder (NMOSD)

A clinical trial to look at the long-term safety and effects of satralizumab in people with neuromyelitis optica spectrum disorder.

A Study to Evaluate the Safety and Efficacy of Satralizumab in Participants With Neuromyelitis Optica Spectrum Disorder (NMOSD)

Trial Status Completed	Trial Runs In 18 Countries	Trial Identifier NCT04660539 2020-003413-35 WN42349
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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 multicenter, single-arm, open-label study will evaluate the long-term safety and efficacy of satralizumab in participants with neuromyelitis optica spectrum disorder (NMOSD) who completed open-label extension (OLE) period of studies BN40898 and BN40900. Participants will receive satralizumab as monotherapy or in combination with one of the following background immunosuppressive treatments: azathioprine (AZA), mycophenolate mofetil (MMF), or oral corticosteroids.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT04660539 2020-003413-35 WN42349
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥18 Years

Healthy Volunteers
No

How does the SAKuraMoon clinical trial work?

This clinical trial is recruiting people who have a type of disease called neuromyelitis optica spectrum disorder or NMOSD. In order to take part, patients must be receiving ongoing treatment with satralizumab as part of either the BN40898 (also called 'SAkuraSky') or BN40900 (also called 'SAkuraStar') clinical trials. Patients who have completed either of these studies will be eligible for this clinical trial. The purpose of this clinical trial is to look at the long-term safety and effects of satralizumab in patients who have participated in either of these two clinical trials and are willing to continue with satralizumab treatment.

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How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed with neuromyelitis optica spectrum disorder and participated in either the BN40898 ('SAkuraSky') or BN40900 ('SAkuraStar') studies. If you are pregnant or breast feeding, you will not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. They will give you all the information you need to make your decision about taking 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, women who can become pregnant will need to either not have heterosexual intercourse or use contraceptives for safety reasons.

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

Everyone who joins this clinical trial will continue to be given satralizumab as an injection under the skin into the abdomen or thigh every 4 weeks. You may also continue to be given other treatments known as 'immunosuppressants', such as azathioprine (or AZA), mycophenolate mofetil (or MMF), or oral corticosteroids.

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

You will be given satralizumab for up to 3 years. You will receive treatment every 4 weeks. Treatment may be given in the clinic, or self-administered at home with a prefilled syringe.

You are free to stop this treatment at any time.

You will still be seen regularly by the clinical trial doctor at least every 12 to 24 weeks. These hospital visits will include the same checks to see how you are responding to the treatment and physical examinations and laboratory tests that you are used to from your current study. Any side effects that you may be having will be assessed throughout treatment with satralizumab and for a further 3 months after treatment is completed.

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 For Patient page or follow this link to ClinicalTrials.gov: <https://clinicaltrials.gov/ct2/show/NCT04660539>

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