ForPatients
by Roche

Neuromyelitis optica spectrum disorder (NMOSD)

A clinical trial to look at how the body processes satralizumab in children with neuromyelitis optica spectrum disorder (NMOSD)

A Study To Evaluate Pharmacokinetics, Efficacy, Safety, Tolerability, And Pharmacodynamics Of Satralizumab In Pediatric Patients With Aquaporin-4 Antibody Positive Neuromyelitis Optica Spectrum Disorder (NMOSD)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	6 Countries	NCT05199688 2019-004092-39 WN41733

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, Multicenter, Open-Label, Uncontrolled Study To Evaluate Pharmacokinetics, Efficacy, Safety, Tolerability, And Pharmacodynamics Of Satralizumab In Pediatric Patients With AQP4 Antibody Positive Neuromyelitis Optica Spectrum Disorder (NMOSD)

Trial Summary:

This study will primarily evaluate the pharmacokinetics of satralizumab in pediatric patients aged 2-11 years with anti-aquaporin-4 (AQP4) antibody seropositive neuromyelitis optica spectrum disorder (NMOSD). Efficacy, safety, tolerability, and pharmacodynamics will be evaluated in a descriptive manner, given the small number of patients who will be enrolled in this study.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT05199688 2019-004092-39 WN41733
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#2 Years & # 11 Years	No

How does the SAkuraSun clinical trial work?

This clinical trial is recruiting patients aged 2–11 years, who have a type of disease called neuromyelitis optica spectrum disorder (NMOSD). In order to take part, patients must have been diagnosed with a specific type of NMOSD and have proteins called AQP4 antibodies present in their blood.

The purpose of this clinical trial is to understand the way the body processes satralizumab, and how safe and effective it is in children with NMOSD.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, your child must be aged 2–11 years and have been diagnosed with NMOSD according to certain criteria. Your child must also weigh at least 10 kg and have had at least one attack of NMOSD symptoms in the last year, prior to entering the clinical trial.

If your child has certain other medical conditions or has previously taken certain medicines, they may not be able to take part in this clinical trial. Certain types of vaccinations (live and attenuated [weakened] vaccines) are not allowed within six weeks before starting the clinical trial and during the clinical trial.

If you think this clinical trial may be suitable for your child and you would like them to take part, please talk to their doctor. If their doctor thinks that your child 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 your child taking part in the clinical trial. You can also find the clinical trial locations on this page.

Your child will have some further tests to make sure they will be able to take the treatment given in this clinical trial. Some of these tests or procedures may be part of your child's regular medical care. They may be done even if your child does not take part in the clinical trial. If your child has 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 your child taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want your child to take part.

While taking part in the clinical trial, female patients of childbearing potential 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 four parts: the screening period, the main treatment period, the optional extension and safety follow-up.

In the main treatment period, everyone who joins the clinical trial will be given satralizumab, as an injection under the skin for 48 weeks. Your child's body weight will determine the dose of satralizumab that they receive. They will be put into one of three groups depending on their body weight:

- If your child weighs at least 10 kg and less than 20 kg, they will be given 60 mg of satralizumab every six weeks
- If your child weighs at least 20 kg and less than 40 kg, they will be given 60 mg of satralizumab at Weeks 0, 2 and 4, and then every four weeks
- If your child weighs 40 kg or more, they will be given 120 mg of satralizumab at Weeks 0, 2 and 4, and then every four weeks

If your child's clinical trial doctor thinks it is necessary, your child may continue receiving their regular (background) treatment for NMOSD in addition to satralizumab, to help prevent NMOSD attacks (relapses).

After your child has been given satralizumab for 48 weeks, you will then have the choice of whether your child continues in the optional extension.

If you decide to enter your child into the optional extension, they will continue to receive satralizumab dependent on their body weight until satralizumab becomes widely available for children aged 2–11, or until the clinical trial is discontinued by Roche. This optional extension of the clinical trial could last for up to three and a half years.

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

Your child will have regular scheduled check-ups at the clinic with their clinical trial doctor. During the main treatment period and the optional extension of the clinical trial, your child will also have check-ups over the phone roughly 2–3 weeks after their previous visit, to check for any side effects or symptoms that your child might be having.

Your child is free to stop this treatment at any time. If you decide to stop your child's treatment and leave the clinical trial, your child must complete the safety follow-up period of 24 weeks. Your child must visit the clinic within 4 or 6 weeks of their last dose (depending on the dose they have received), and both 12 and 24 weeks after their last dose. You will also have phone check-ups every 2–3 weeks during this time.

What happens if I am unable to take part in this clinical trial?

If this clinical trial is not suitable for your child, they will not be able to take part. Your doctor may suggest other clinical trials that your child may be able to take part in or other treatments that they can be given. Your child will not lose access to any of their 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/NCT05199688

Trial-identifier: NCT05199688

Inclusion Criteria:

- Age at screening 2-11 years, inclusive
- Body weight at screening >=10 kg
- For female patients of childbearing potential (postmenarchal): agreement to either remain completely abstinent (refrain from heterosexual intercourse) or to use a reliable means of contraception
- Diagnosed as having NMOSD with AQP4 antibody seropositive status as defined by the Wingerchuk 2015 criteria Clinical evidence of at least one documented attack (including first attack) in the last year prior to screening
- Neurological stability for >=30 days prior to both screening and baseline
- Expanded Disability Status Scale (EDSS) 0 to 6.5
- For patients receiving a baseline immunosuppressant treatment and planning to continue on these therapies, treatment must be at stable dose for 4 weeks prior to baseline

Exclusion Criteria:

- Pregnancy or lactation
- Evidence of other demyelinating disease mimicking NMOSD
- Active or presence of recurrent bacterial, viral, fungal, mycobacterial infection, or other infection at baseline
- Evidence of chronic active hepatitis B or C
- Evidence of untreated latent or active tuberculosis (TB)
- Receipt of a live or live-attenuated vaccine within 6 weeks prior to baseline
- History of severe allergic reaction to a biologic agent