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LGI1 Autoimmune Encephalitis NMDAR Autoimmune Encephalitis Autoimmune Encephalitis

A study to compare satralizumab with placebo in people with autoimmune encephalitis

A Study to Evaluate the Efficacy, Safety, Pharmacokinetics (PK), and Pharmacodynamics (PD) of Satralizumab in Participants With Anti-N-methyl-D-aspartic Acid Receptor (NMDAR) or Anti-leucine-rich Glioma-inactivated 1 (LGI1) Encephalitis

Trial Status
Recruiting

Trial Runs In
18 Countries

Trial Identifier
NCT05503264
2021-002395-39,2023-504226-18-00
WN43174

The source of the below information is the publicly available website [ClinicalTrials.gov](https://clinicaltrials.gov). It has been summarised and edited into simpler language.

Trial Summary:

The purpose of this study is to assess the efficacy, safety, PK, and PD of satralizumab in participants with NMDAR and LGI1 encephalitis.

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT05503264 2021-002395-39,2023-504226-18-00 WN43174
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
≥12 Years

Healthy Volunteers
No

1. Why is this study needed?

Encephalitis is a rare disease caused by swelling or inflammation in the brain. It can be an autoimmune disease - when the body attacks healthy cells by mistake. In these cases, it is known as 'autoimmune encephalitis' (AIE). In AIE, proteins called 'antibodies' mistakenly attack healthy tissues and proteins. Usually, antibodies form part of the immune system. This is the body's natural defence against infection or other foreign substances. The most common types of AIE are called 'NMDAR' and 'LGI1' AIE, named after the type of harmful antibody involved.

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Currently, there are no approved treatments for AIE. Doctors use therapies to dampen the immune system, reduce inflammation, stop the body making antibodies, or temporarily remove harmful antibodies from the blood. New, approved treatments are needed for AIE which can be taken for a long period of time, to protect the brain.

This study is testing a medicine called satralizumab. It is being developed to treat NMDAR and LGI1 AIE.

Satralizumab is an experimental medicine. This means health authorities (like the U.S. Food and Drug Administration and European Medicines Agency) have not approved satralizumab for the treatment of AIE. This study aims to compare the effects of satralizumab against non-active medicine (placebo) in people with NMDAR and LGI1 AIE.

2. Who can take part in the study?

People of at least 12 years of age with NMDAR AIE, or at least 18 years old with LGI1 AIE can take part if they have had AIE symptoms for 9 months or less.

People may not be able to take part in this study if they have certain other diseases, such as infections, uncontrolled heart or lung disease, or cancer within the last 5 years. People who have been given certain treatments, such as those that affect the immune system, may not be able to take part. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

People will be screened to check if they are able to participate in the study. The screening period will take place from 1 month before the start of treatment.

This is a 'placebo-controlled' study. This means that participants are put in a group that will receive a medicine or a group that will receive 'placebo' (a medicine that contains no active ingredients but looks the same and is taken in the same way as the study medicine). Comparing results from the different groups helps researchers know if any changes seen result from the study medicine or occur by chance.

Everyone who joins this study will be placed into 1 of 2 groups randomly (like flipping a coin) and given either satralizumab OR placebo, given as an injection under the skin 3 times over the first month then once every month. Participants will have an equal chance of being placed in either group.

This is a double-blinded study. This means that neither the participants in the study nor the team running it will know which treatment is being given until the study is over. This is done to make sure that the results of the treatment are not affected by what people

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expected from the received treatment. However, the study doctor can find out which group the participant is in, if the participants' safety is at risk.

Participants already taking medicines to dampen their immune system (mycophenolate, cyclophosphamide or azathioprine) can continue taking them at the same dose - this is called 'background therapy'. If disease worsens and a participant needs to increase their dose of background therapy or have another treatment during the study - this is called 'rescue therapy'.

After 1 year of treatment is a 2-year extension phase. In the extension phase, participants can choose to continue taking the 'double-blinded' study medicine, start taking satralizumab (with the participant and study doctor knowing which medicine is being given - known as 'open-label' treatment), or stop taking the study medicine and continue visits for assessments.

During this study, the study doctor will see participants every 2 weeks in the first month, then every month for about 1 year. The study doctors will see how well the treatment is working and any unwanted effects participants may have. In the extension phase, participants who start open-label satralizumab will repeat this visit schedule for 6 months. From then, monthly treatment may be given at the participants' home if they prefer, and doctors will telephone the participant to check on their wellbeing after each treatment. Those who continue monthly double-blind treatment may also be given it at home from the start of the extension phase. Study visits will be every 3 months if treatment is being given in the home.

Participants will have a follow-up visit 3 months after completing the study treatment, during which the study doctor will check on the participant's wellbeing. Participants under the age of 18 when the study started will have an extra visit 6 months after finishing the study treatment. Total time of participation in the study will be 3 to 5 years, depending on when a participant joins the study. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicine has worked are:

- The number of participants with improved symptoms and ability to carry out daily activities without needing rescue therapy after 6 months of treatment
- The number and seriousness of unwanted effects

Other key results measured in the study include:

- The amount of time between starting treatment and improved symptoms and ability to carry out daily activities without rescue therapy
- The amount of time between starting treatment and rescue therapy being needed

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- The number of participants who do not have any seizures for at least 1 month without rescue therapy up to 6 months after starting treatment
- Change in the severity of AIE symptoms from the start of the study to 6 months
- How well the brain functions (thinking, remembering, and reasoning) at 6 months

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

Risks associated with satralizumab Participants may have unwanted effects of the experimental drug used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Participants will be told about the known unwanted effects of satralizumab and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include infections, an allergic reaction to the drug, a reaction on the skin where it has been pricked with a needle to give a treatment, joint pain, and a low level of a type of white blood cell (neutrophils). Known unwanted effects of an injection under the skin include redness, swelling or rash on the skin where it has been pricked with a needle to give a treatment. The study medicine may be harmful to an unborn baby. Women must take precautions to avoid exposing an unborn baby to the study treatment.