What are we trying to learn about relapsing Neuromyelitis Optica (NMO) in this study?

 The purpose of this study is to determine if the investigational medicine is safe and effective in preventing relapse in people with relapsing NMO.

Clinical testing only occurs after a medicine has completed a number of steps to evaluate its safety and potential efficacy.

- The Authorities require that a potential treatment be adequately tested before it can be approved to be available for patients.
- Every trial follows an extensive and carefully monitored process that focuses on the safety of the patient who participates.



The doctor will discuss the possible side effects with you and explain the risks and potential benefits prior to enrollment. If you are considering participating in a trial, the researchers will explain the details of the study and give you a document to sign. This document includes details about the study, the risks and potential benefits of the study, and who to contact for further information.

Who is eligible to be part of this study?

You may be eligible to participate if you are an adult, age 18 years or older with:



A confirmed diagnosis of relapsing NMO or NMO-SD and test positive for the NMO antibody in your blood



At least 2 relapses in the last 12 months **or**

3 relapses in the last 24 months (with at least 1 relapse in the last 12 months)

If you qualify and decide to participate in this study, you will be randomly assigned to receive either active study medication or inactive study drug (placebo).



Your chances of receiving active study medication vs placebo

You may continue to receive your current NMO treatment. Your doctor will discuss this with you.

Patients who complete the study may have the option to enroll in a separate study in which all patients receive the active medication. Consult with your doctor about participation.

What are the stages of the study?

- **1. Screening:** Your doctor will determine if you are eligible for the study.
- 2. Treatment: You will receive active drug or placebo given by intravenous infusion.

 Treatment will be given every week for the first 5 weeks, and then every 2 weeks afterwards.

 This treatment period will last potentially as long as 2 years.
- 3. Relapse or Attack: If you have a relapse, your doctor will treat you accordingly and you will be monitored for an additional 6 weeks.
- **4. Follow up Period:** After successful completion of the study, you have the option to enroll in a follow up study, where eligible patients will all receive the active study medication.

By participating you may...

- Gain access to an investigational medicine to potentially treat relapsing NMO/NMO-SD
- Help advance knowledge about the relapses in NMO/NMO-SD

What is known about NMO?

NMO is a rare disorder caused by the immune system attacking the body's healthy cells, with attacks directed mostly against the eyes and the spinal cord

This causes inflammation of the spinal cord and optic nerve, which can cause loss of vision and loss of mobility and sensation.

- Many patients continue to relapse (have attacks) despite treatment
- Disability may get worse with every relapse

Women are more likely to have NMO than men



As high as 9:1

If you have NMO, it's likely you've tested positive for the NMO antibody



Relapsing NMO patients who have tested positive for NMO antibody up to 80%

If you have relapsing NMO, you are not alone



Patients with NMO who will have relapses 90%



Call your doctor to learn more about the study.

For additional information, visit
Alexionclinicaltrials.com/nmo.html
or
clinicaltrials.gov/ct2/show/NCT01892345

Sources:

- 1. www.nih.gov/health/clinicaltrials/basics.htm#4
- 2. www.guthyjacksonfoundation.org/nmo-fag/
- Jarius S, Wildemann B, Paul F.Neuromyelitis Optica:clinical features, immunopathogenesis and treatment. Clin Exp Immun 2014:176:149-164





-Neil Armstrong



If you have relapsing Neuromyelitis Optica (NMO) or NMO Spectrum Disorder (NMO-SD)

You may be eligible to participate in a new research study for the prevention of relapses

