A DOUBLE BLIND TRIAL TO EVALUATE THE SAFETY AND EFFICACY OF ECULIZUMAB IN RELAPSING NMO PATIENTS

SPONSORED BY ALEXION PHARMACEUTICALS

STUDY DETAILS

The primary objective of the study is to assess the efficacy and safety of eculizumab treatment as compared to placebo in relapsing NMO patients using a time to first relapse study design. This is a randomized double blind study, where participants will receive eculizumab or placebo and neither the participant nor the study doctor or their staff will know who received the drug or placebo. In this study participants will have a 67% chance of receiving eculizumab and a 33% chance of receiving placebo. The medication is given intravenously, initially weekly for 5 weeks and then every 2 weeks.

Eculizumab is not approved for treatment of NMO. Eculizumab is a monoclonal antibody that blocks one component of the complement pathway, part of the immune system. Activation of the complement pathway is believed in part to be responsible for relapses in NMO. A pilot study of eculizumab in 14 female NMO patients suggested that eculizumab can reduce the risk of relapse. This study is intended to confirm that finding.

CONTACT INFORMATION

If you are interested in participating, please contact the sponsor by email at clinicaltrials@alxn.com or call 203-272-ALXN

You may also contact:

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http://clinicaltrials.gov/ct2/show/study/NCT01892345?term=ALexion&rank=5

ELIGIBLE PARTICIPANTS

Participants maybe eligible if they are at least 18 years old, have a positive test for the NMO IgG antibody and have experienced 2-3 relapses in the last 2 years with at least one relapse in the last 12 months.

This is an "add on study," and patients can continue to be on their current NMO medications and receive the study medication. The duration of the study is 2 years. If participants have a relapse, the study will end; however there is a second study participants may be eligible to enroll where all patients will receive eculizumab.

As with all medications there are potential side effects, which will be discussed prior to enrollment and detailed in the informed consent.

THE TMA'S 'ASK THE EXPERT' PODCAST SERIES NOW AVAILABLE ON ITUNES!

Thank you to those who joined the podcasts on "Understanding Pediatric ADEM, NMO and TM" in July 2014 and "Understanding Clinical Trials in NMO and TM" in August 2014 as part of TMA's Ask the Expert podcast series. The podcast sessions provide an avenue for individuals diagnosed with these disorders and their family members to ask questions of experts who specialize in these disorders. The physician-experts on the podcast panels in July and August were Dr. Teri Schreiner from the University of Colorado School of Medicine and Children's Hospital Colorado, Dr. Benjamin Greenberg from University of Texas Southwestern in Dallas, Dr. Michael Levy from Johns Hopkins Hospital in Baltimore, and Dr. Dean Wingerchuk from the Mayo Clinic in Scottsdale.

The podcast recordings have not only been made available on our website at https://myelitis.org/education/podcasts, but you can also find all recordings on iTunes by going to:

https://itunes.apple.com/us/podcast/tma-ask-experts-podcast-series/id893008309?mt=2

You will be able to listen and download all prior podcasts for free! Don't forget to stay tuned for more TMA podcasts featuring leading medical experts in the field of rare neuro-immune disorders - http://myelitis.org/education/podcasts.