The Effect of Pregnancy on Neuromyelitis Optica

INVESTIGATOR

Eric Klawiter, MD

STUDY SITE

Massachusetts General Hospital,
Harvard MedicalSchool, Boston, MA

STUDY DETAILS

This research is being conducted to study the effect of pregnancy on Neuromyelitis Optica (NMO). It commonly affects females of childbearing age. To date, women's health issues in NMO have not been studied in detail. Determining the effect of pregnancy on the NMO disease course is of great importance in counseling patients on family planning. Information will also be gathered on the incidence of complications of pregnancy and the incidence of miscarriages.

CONTACT INFORMATION

If you are interested in participating, please contact: Dr. Eric Klawiter at 617-726-7643. Please be prepared to leave a detailed message, including the name of the study and your contact information (so that you can receive a confidential message in response).

ELIGIBLE PARTICIPANTS

The study is enrolling females age 18 or older with NMO. Participants do not need to have been pregnant in the past to participate. Participants can be NMO antibody positive or negative as long as they carry the diagnosis of NMO. Participation would involve completing a survey that will be administered over the phone and should take 10-20 minutes of your time. There is no monetary compensation. There is no cost to you. You will not receive any personal health benefits as a result of your participation in this research study. We hope that the results will help us better understand NMO, and might benefit patients with NMO in the future. Your participation is voluntary.

WE DON'T WANT TO LOSE YOU

Please keep us informed of any changes to your mailing address, your phone number and your email address. You can send changes either by going online to http://tinyurl.com/bswg6yp or via email at info@myelitis.org. For those of you who wish to receive our communications by postal mail, the Association does all of our mailings using the postal service bulk, not-for-profit rate within the United States and our territories and protectorates. We save a considerable amount of money by doing our mailings this way. Unfortunately, when you move and don't provide us with the change, our mail will not be forwarded to you after your grace period, and this class of mail is not returned to the sender. The cost to the Association is substantial. These are wasted printing and postage costs. Please keep your information current. Your diligence is greatly appreciated.

IN THEIR OWN WORDS ARTICLE

In each issue of the newsletters, we will bring you a column that presents the experiences of our members. The stories are presented In Their Own Words by way of letters we receive from members like you. We are most appreciative of your willingness to share very personal stories. It is our hope that through the sharing of these experiences, we will all learn something about each other and about ourselves. It is our hope that the stories will help us all realize that we are not alone. It is important to bear in mind that the stories are not written by The Transverse Myelitis Association but come from our members. It is also important to note that the newsletters are archived on our web site. Should someone do an Internet search of your name, your article is likely to be identified in his or her search results. You may submit your stories by sending them either by email or through the postal service to Sandy Siegel. Please be sure to clearly state that The Transverse Myelitis Association has your permission to publish your article.

Safety and Efficacy of Sustained release DALFAMPRIDINE IN TRANSVERSE MYELITIS

STUDY DETAILS

The goal of this clinical trial is to test the efficacy of dalfampridine in patients diagnosed with Transverse Myelitis. Dalfampridine is a sustained-release potassium channel blocker that has been shown to be effective in improving gait and other neurologic functions in multiple sclerosis. Dalfampridine has the potential to improve gait and neurologic function in patients with transverse myelitis because of a similar pathogenic process with multiple sclerosis.

The clinical trial will focus on monophasic Transverse Myelitis (TM) and will evaluate the efficacy of dalfampridine in primary neurologic outcome – 25-foot timed walk, and several secondary outcomes including valid behavioral and neurophysiological measures. To better understand the mechanisms underlying the proposed behavioral gains, the investigators will use Transcranial Magnetic Stimulation as the neurophysiologic measure to identify changes in corticomotor excitability in the spinal cord.

All study participants will be randomized for the first double-blinded 8-week part of the study with 25-foot timed walking assessments every 2 weeks. At the conclusion of this first 10-week trial, subjects will be crossed over to the other therapy for another 8 weeks and 25-foot timed walking assessments will again be done every 2 weeks.

INVESTIGATOR

Michael Levy, MD, PhD

STUDY SITE

Johns Hopkins University
Baltimore, MD

CONTACT INFORMATION

Maureen Mealy, RN
hopkinstmcenter@jhmi.edu

ELEGIBLE PARTICIPANTS

Patients (18-70 years) diagnosed with monophasic transverse myelitis confirmed by MRI will be eligible to participate in this study.

Diagnosis of recurrent myelitis or multiple sclerosis is an exclusion criteria for the study; however, patients may have a diagnosis of neuromyelitis optica, lupus, sarcoidosis or other rheumatologic or systemic disorder in the setting of monophasic myelitis.

Other exclusion criteria include:

- History Of Seizure(S).
- Pregnancy Or Positive Pregnancy Test (Mandatory Test For All Women Aged 18-55 To Be Done At First Screening Visit).
- Known Allergy To Dalfampridine Or Any Other Formulation Of 4-Aminopyridine.
- Patients Unable To Walk.
- Patients With History Of Severe Alcohol Or Drug Abuse, Severe Psychiatric Illness Like Severe Depression, Poor Motivational Capacity, Or Severe Language Disturbances, Particularly Of Receptive Nature Or With Serious Cognitive Deficits (Defined As Equivalent To A Mini-Mental State Exam Score Of 23 Or Less).
- Patients With Severe Uncontrolled Medical Problems (E.G. Hypertension, Cardiovascular Disease, Severe Rheumatoid Arthritis, Active Joint Deformity Of Arthritic Origin, Active Cancer Or Renal Disease, Any Kind Of End-Stage Pulmonary Or Cardiovascular Disease, Claudication, Uncontrolled Epilepsy Or Others).

Efficacy & Safety Study of SA237 as Monotherapy to Treat NMO And NMOSD

SPONSORED BY CHUGAI PHARMACEUTICALS

STUDY DETAILS

This research is being conducted to evaluate the efficacy, safety, pharmacodynamic, pharmacokinetic and immunogenic profiles of a humanized anti-human IL-6R neutralizing monoclonal antibody (SA237) in patients with Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorder (NMOSD). This study is being conducted in the US and Canada and will enroll seventy (70) patients to participate in this research.

Mechanism of Action: SA237 is a humanized anti-human IL-6R neutralizing monoclonal antibody that was designed by applying recycling antibody technology to the approved anti-IL6 receptor antibody, tocilizumab, which is currently marketed as a treatment for rheumatoid arthritis (RA), systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis and Castleman's disease. The recycling antibody technology enabled SA237 to bind to IL-6 receptor multiple times and be slowly cleared from plasma, which is expected to contribute to improvement and is convenient with once monthly dosing frequency. The longer plasma half-life of SA237 compared with tocilizumab was confirmed based on the results of a non-clinical study and a Phase 1 study in healthy volunteers.

ELIGIBLE PARTICIPANTS

Inclusion Criteria:

1. NMO or NMOSD
2. Age 18 to 74 years, inclusive at the time of informed consent.

Exclusion Criteria:

1. Pregnancy or lactation.
2. Evidence of other demyelinating disease or PML.
3. Known active infection (excluding fungal infections of nail beds or caries dentium) within 4 weeks prior to baseline.

CONTACT INFORMATION

If you are interested in participating, please contact:

Clinical trials information clinical-trials@chugai-pharm.co.jp

SA237 Clinical trial sa237@chugai-pharm.co.jp

http://clinicaltrials.gov/ct2/show/study/NCT02073279?term=SA237&rank=1

For more information on the European/Asian trial, please visit:
https://www.clinicaltrialsregister.eu/ctr-search/search?query=SA237

SUBSCRIBE TO THE TMA BLOG!

Have you read the **TMA BLOG** (https://myelitis.org/category/resources/tma-blog) lately? We publish weekly stories and articles written by individuals living with rare neuro-immune diseases, caregivers and families, as well as leading researchers and clinicians. The blog covers a wide variety of relevant topics, including stories about your experiences living with a rare neuro-immune disease, clinical care and management updates, new research studies, TMA awareness and education program announcements.

You don't have to wait for the latest publication of the TMA Newsletter or try to remember to visit the TMA website in order to receive the most up-to-date information on the latest research and findings in the field of rare neuro-immune disorders. It's easy to stay informed about the latest events, programs and activities of The Transverse Myelitis Association. You can have all of this information delivered directly to your inbox so you won't miss a thing! To receive a weekly email with our latest blog posts in your inbox, **please go to http://eepurl.com/xuoGr.**

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:

Warren W. Wasiewski MD | VP Clinical Development Neurology
Alexion Pharmaceuticals Inc. | 203-699-7701

Idil Cavus, MD | Medical Director, Neurology
Alexion Pharmaceuticals Inc. | 203-699-7859

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 & Managing Neuropathic Pain" in May 2014 and "The Role of Exercise and Rehabilitation in Non-Traumatic Spinal Cord Injury" in June 2014 as part of TMA's Ask the Expert podcast series. With over 215 members registered, the podcast sessions provided 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 panel were Dr. Daniel Becker from the International Neurorehabilitation Institute in Lutherville, Dr. Allen DeSena & Dr. Melanie Farrar from University of Texas Southwestern in Dallas, Dr. Kathleen Zackowski from Johns Hopkins Medicine in Baltimore, and Dr. Scott Newsome from Johns Hopkins Transverse Myelitis Center in Baltimore.

The podcast recording has not only been made available on our website https://myelitis.org/education/podcasts; you are now also able 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 by going to http://myelitis.org/education/podcasts.

An open-label Study of Bevacizumab for the Treatment of Acute Optic Neuritis and/or Transverse Myelitis in Neuromyelitis Optica and Neuromyelitis Optica Spectrum Disorder

INVESTIGATOR

Michael Levy, MD, PhD

STUDY SITE

Johns Hopkins University
Baltimore, MD

STUDY DETAILS

NMO is a severe, demyelinating autoimmune disease of the central nervous system that preferentially affects the optic nerves and spinal cord. Although historically considered a subtype of multiple sclerosis (MS) with overlapping symptoms, NMO is distinct radiologically and prognostically, and has a pathophysiology unresponsive to typical MS treatments.

This is a phase 2 investigator-initiated interventional trial of bevacizumab to evaluate the tolerability/safety and preliminary efficacy of bevacizumab as add-on therapy for treatment of acute optic neuritis and/or transverse myelitis in neuromyelitis optica (NMO) and neuromyelitis optica spectrum disorder (NMOSD). A single infusion of bevacizumab is added to standard-of-care high dose steroids and an additional dose of bevacizumab is added to plasma exchange (if necessary). The primary outcomes are clinical changes in the Expanded Disability Severity Scale, Timed 25-foot Walk and Low Contrast Visual Acuity, MRI parameters and safety.

ELIGIBLE PARTICIPANTS

Patients may be eligible who are between the ages of 18 and 70 who present with acute optic neuritis and/or transverse myelitis and have a known or suspected diagnosis of NMO or NMO spectrum disorder. Female participants must not be pregnant and must commit to not becoming pregnant in the next 6 months from time of consent.

CONTACT INFORMATION

Maureen Mealy, RN
hopkinstmcenter@jhmi.edu

A Safety, Tolerability and Efficacy Study of V158866 in Central Neuropathic Pain Following Spinal Cord Injury

INVESTIGATOR

Christine N. Sang, MD, MPH

STUDY SITE

Brigham and Women's Hospital
Boston, MA

STUDY DETAILS

V158866 is an active inhibitor of FAAH1, an enzyme that metabolizes the endocannabinoid called Anandamide (AEA). It is hypothesized that inhibition of FAAH1 can decrease pain without generating side effects in non-activated pathways. Therefore, the primary objective of this study is to investigate the safety and tolerability of V158866 in subjects with central neuropathic pain following spinal cord injury (both traumatic and non-traumatic) and evaluate its analgesic and anti-hyperalgesic effect. The study will consist of four overnight visits to the hospital. All travel to and from the hospital will be reimbursed.

CONTACT INFORMATION

If you are interested in participating, please contact the Translational Pain Research Group by email at paintrials@partners.org or call 617-525-7246.

http://clinicaltrials.gov/ct2/show/NCT01748695?term=V158866&rank=2

ELEGIBLE PARTICIPANTS

Male and females (not of child-bearing potential) between 18 – 65 years old with a documented spinal cord injury will be eligible to participate in this study. Participants must have central neuropathic pain that is of at least moderate intensity, daily for at least 3 months before study entry. This study will be of no cost to the participant. Your participation is voluntary.