SAFETY AND EFFICACY OF SUSTAINED RELEASE DALFAMPRIDINE IN TRANSVERSE MYELITIS

INVESTIGATOR

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STUDY SITE

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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.

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).