

RESEARCH STUDY: ADULT VOLUNTEERS WITH TM, MS, OR NMO NEEDED FIRST-STIM

CNS Growth <u>Factor Release</u> and Changes in the <u>Inflammatory</u> Environment in <u>Response to Electrical Stimulation in Subjects with <u>Inflammatory Myelopathies</u>.</u>

WHO: Adults, age 18-65 with diagnosis of transverse myelitis, or multiple sclerosis, or neuromyelitis optica.

WHAT: This research is being done to study the effect of functional electrical stimulation (FES) cycling on factors in blood and spinal cord in people with spinal cord inflammation. FES cycling is a method of applying low level electrical currents to the leg and hip muscles to cause the weakened or paralyzed muscles to contract and produce a cycling motion of the legs.

You will be assigned by chance (like flipping a coin) to one of 4 groups:

Group 1: 1 hourly FES cycling session/week for 3 weeks (maximum 5 visits)

Group 2: 3 hourly FES cycling sessions/week for 3 weeks (maximum 11 visits)

Group 3: 5 hourly FES cycling sessions/week for 3 weeks (maximum 17 visits)

Group 4: 3 hourly cycling without FES sessions/week for 3 weeks (maximum 11 visits)

During the Initial, and Final Visits you will complete some tests that will last up to 3 hours. These tests include lumbar puncture, blood draw, assessing your spasticity, mood, and a neurological exam.

RISKS: Possible risk factors associated with the testing and cycling are:

- Pain from electrical pulses.
- Headaches and pain from the lumbar puncture.
- Time commitment and missing work/school

BENEFITS: There is no known benefit to you for participating in this study. This study may benefit others in the future by helping understand what the optimal amount of FES ergometry is to contribute to an improved quality of life for people spinal cord inflammation.

WHERE: The International Center for Spinal Cord Injury at Kennedy Krieger Institute 707 North Broadway, Baltimore, MD

CONTACT: Research Coordinator at the International Center for Spinal Cord Injury (443) 923-9235 or clinicaltrials@spinalcordrecovery.org



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