



ADULTS WITH SPINAL CORD INJURY NEEDED

Patterned FES Ergometry of Arm and Shoulder in Individuals with Spinal Cord Injury

WHO: Adults, age 18-55 with cervical spinal cord injury.

WHAT: This research is being done to find out if Functional Electrical Stimulation (FES) arm cycling can improve the function of people with cervical spinal cord injury that paralyzes both arms and legs. FES arm cycling is a method of applying low level electrical currents to the arm and shoulder muscles to cause the weakened or paralyzed muscles to contract and produce a cycling motion of the arms.

You will be randomly assigned by chance (like flipping a coin) to either group 1, where you will first do arm cycling with FES for 4 months followed by exercises without FES for 4 months, or to group 2 where you will first do exercises without FES for 4 months followed with arm cycling with FES for 4 months. You will have a 50% (1 out of 2) chance to start with FES arm cycling and a 50% (1 out of 2) chance to start exercising without FES.

You will be asked to come to the International Center for Spinal Cord Injury (ICSCI) for 1 hour, 3 times a week for 4 months to do either the arm cycling with FES, or the exercise without FES.

You will be in this study for 12 months. A total of 99 visits will be scheduled during this period, including an Initial Visit after enrollment, 48 1st type treatment Visits, a Visit at 4 months after completing first type of treatment, a Visit at 5 month after 1 month break between the two treatments, 48 2nd type treatment Visits, a Visit at 9 month after finishing the second type of treatment, and a Final Visit at 12 months.

During the Initial, 4 month, 5 month, 9 month and 12 month Visits, you will complete some tests that will last 4 hours. These tests include taking an X-Ray of your shoulders, assessing how you are able to use your arms and hands, your pain and spasticity, and a neurological exam.

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

- pain from electrical pulses.
- exposure to radiation from the x-ray.

BENEFITS: There is no known benefit to you for participating in this study, although it is possible that you might benefit from arm cycling with FES by increasing your muscle mass and strength, decreasing your muscle tone, and your cardiovascular conditioning might improve as well. This study may benefit others in the future by helping understand how upper extremity ergometry with FES might contribute to an improved quality of life for people with cervical spinal cord injuries. Recruitment benefit after completion is \$250.00

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



International Center for Spinal Cord Injury
at Kennedy Krieger Institute
Research. Restoration. Recovery.

Principal Investigator: Dr. Cristina Sadowsky, MD

IRB protocol: NA_00014481

Sponsor: Department of Defense (DOD) Telemedicine and Advanced Technology Research Center (TATRC); Proposal: 08284002 and 09181006

Version/Date: 3.2, 07-Sep-2010



Approved September 30, 2010