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CLEVELAND FES CENTER

Facilitating Ambulation after Incomplete SCI with FES

Information about research participation for individuals with incomplete Spinal Cord Injury



Overview

What is the purpose of this research study?

- To evaluate the effectiveness of Functional Electrical Stimulation (FES) to improve walking in persons with incomplete spinal cord injury (SCI)

What is FES?

- FES is a rehabilitative technique using low-level electrical current to enhance the function of paralyzed muscles
- The combination of FES and volitional muscle control can improve a partially paralyzed individual's ability to walk

How does FES work?

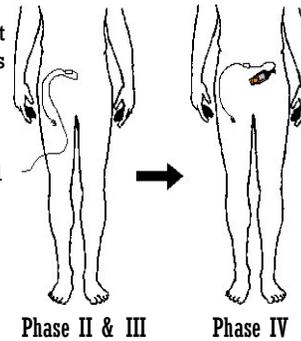
- A device sends small electrical currents through electrodes to excite the nerves and cause the muscles to contract
- The electrodes can be external to the body (surface of the skin) or internal (implanted under the skin directly in contact with the muscles).

Funding for this study is provided by the Department of Veterans Affairs and is being performed in collaboration with the Louis Stokes Cleveland VA Medical Center, Case Western Reserve University and the Cleveland FES Center

Participant Inclusion and Exclusion Criteria

The inclusion criteria for the study are as follows:

1. Skeletal maturity and ability to understand and sign the informed consents (age greater than 18 years)
2. Low cervical or thoracic incomplete spinal cord injuries (C6-T12)
3. ASIA Impairment Scale C (motor and sensory sparing). Must be able to stand, but is either unable or requires great effort when taking steps
4. Time post injury greater than six months (neurological and emotional stability)
5. Intact lower motor neurons (presence of spasticity in legs)
6. No psychological problems or chemical dependency
7. Range of motion within normal limits (no greater than five degree flexion limitation at the hip, full extension at the knee, and ability to attain neutral ankle position)
8. No acute orthopedic or medical complications
9. Adequate social support and willingness to comply with follow-up procedures



Criteria for exclusion include the following:

1. Pacemaker
2. Cardiac arrhythmia
3. Pregnancy
4. Severe contractures of any major joint of upper or lower extremities
5. Seizure disorder
6. Obesity
7. Untreated substance abuse
8. Immunodeficiency
9. Frequent urinary tract infections
10. Presence of decubitus ulcers

Description of the Study

It consists of four distinct phases:

Phase I: Screening— Physical and psychosocial status is determined in order to see if you can participate safely in the study

Phase II: Treatment— The therapeutic effects of exercise, treadmill and overground training with FES on strength, endurance and walking ability is evaluated. Stimulating electrodes are inserted into your muscles and connected to an external stimulator by temporary lead wires that exit through the skin. Treatment will require at least 3 sessions per week for 12 weeks at the Motion Study Laboratory of the Louis Stokes Cleveland Department of Veterans Affairs Medical Center.

Phase III: EMG Control— Methods of controlling stimulation and integrating it with your own voluntary muscle contractions during walking will be evaluated. The EMG is a small electrical signal generated by a contracting muscle. This part of the study will focus on using the EMG from one of your unparalyzed muscles to control stimulation.

Phase IV: Implant— Depending on the outcome of Phases I-III, you may have the option to receive a surgically implanted stimulator. Additional walking tests and long term monitoring of the implant will be required

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