STIMO

First-in-man study
Invitation to participate

Interested in participating or do you have any questions?

Please find more information on: www.clinicaltrials.gov
Or contact:
Molywan Vat (CHUV, Neurosurgery Department), molywan.vat@chuv.ch
Dr Jocelyne Bloch (CHUV, Neurosurgery Department), jocelyne.bloch@chuv.ch
Centre Hospitalier Universitaire Vaudois (CHUV), Lausanne, Canton de Vaud, Switzerland, 1011, Tel.: +41 21 314 12 93

Flyer Version 1.1 - 8-12-2016

What is STIMO?

Dear Patient,
We would like to inform you of a new clinical study initiated at the University Hospital of Lausanne (CHUV) for the treatment of persons with an incomplete spinal cord lesion. The study is called 'STIMO'.
STIMO is an innovative clinical study to evaluate the safety and efficacy of the combination of two different treatments:
• Electrical stimulation of the spinal cord.
• Overground body weight support rehabilitation training.

A decade of research in animal models provided strong evidence suggesting that the combination of both treatments may synergistically improve the neurological function of the legs, and may thus result in improved walking capabilities.

Who can benefit?

People with chronic incomplete spinal cord injury (ASIA C or D) located above the T10 vertebra.

What benefits are expected?

The aim of the study is to allow the participants to walk better and faster. Rigorous scientific evaluations will be conducted prior to the surgical implantation and at regular intervals throughout the study to quantify improvements. As this is the first study evaluating this therapeutic approach in people with incomplete spinal cord injury, success is not guaranteed. However, the potential benefits outweigh the potential risks.

Study Summary

The study lasts about 9 to 11 months for each participant, from signing the informed consent to the final test of the study. The period can be divided in 3 distinct phases:

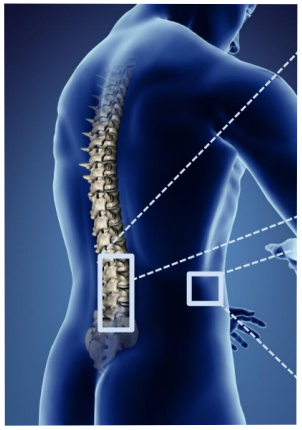
• **Pre-implant**: about 6 to 8 weeks from the signed informed consent to the surgical implantation. During this phase, the participant receives 9 sessions of training in the overground body weight support device, over a period of 3 weeks. He/she will also participate in a number of evaluations that will primarily take place in Lausanne. A full day of assessments will also be conducted at the Spinal Cord Injury Center, University Hospital Balgrist, Zurich.

• **Surgical implantation and stimulation optimization**: about 6 to 8 weeks, including the surgical implantation of the epidural lead over the lumbar spinal cord, and of the neurostimulator. During this phase, the stimulation parameters are optimized in order to facilitate a range of motor activities, including walking, standing and sit-to-stand.

• **Rehabilitative training and final evaluation**: the rehabilitation program takes place 4 days per week during a period of 5 months. Motor training is conducted during overground walking using the state-of-the-art body weight support system, as well as during standing and sit-to-stand. Electrical spinal cord stimulation is applied during training to facilitate the motor execution and enhance the reorganization of neural connections. At the end, a final evaluation is conducted in Lausanne and 1 day in Zurich.

During the period that follows the surgical implantation, the participants need to be present in Lausanne 4 days per week until the end of the study (lodging can be provided).

Epidural Electrical Stimulation



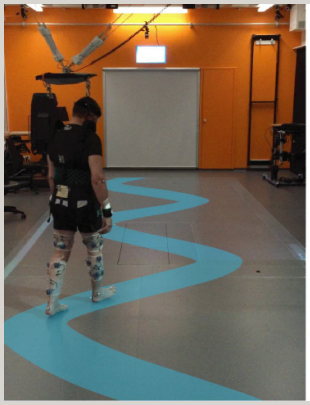
Electrode

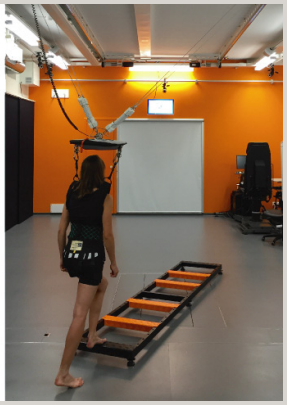
Implanted in the epidural space of the spinal cord. Transmits the electrical pulses from the stimulator into the spinal cord.

Stimulator

Stimulator implanted in a pocket under the skin. Generates the electrical pulses to the electrode.

Overground Body Weight Support Rehabilitation Training





A state-of-the art overground body weight support system allows active movements through a wide range of natural locomotor activities. This system provides optimal bodyweight support while ensuring safety of the participants to prevent falls.