Effect of trans-spinal direct current stimulation and robotic support on the neural motor pathways in healthy and SCI subjects.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON45243

Source
ToetsingOnline

Brief title
Effect of tsDCS and robotic support on the neural motor pathways

Condition

- Spinal cord and nerve root disorders

Synonym
"Spinal Cord Injury" and "Paraplegia"

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: ZonMW,TMS

Intervention

Keyword: Neurorehabilitation, Robotic gait trainer, Spinal Cord Injury, trans-spinal direct current stimulation

Outcome measures

Primary outcome

Since this protocol does not describe a single experiment but a framework according to which a set of studies and experiments can be designed, there are many possible main outcome parameters which depend on the measurement techniques that will be employed. These may or may not all be part of a single study. The measurements that can be conducted before, during and after the main interventions are the assessments of:

* H-Reflex

* Somatosensory Evoked Potentials (SSEPs)

* Motor Evoked Potentials (MEPs)

* Walking Characteristics

Secondary outcome

* Subject physical or mental discomfort during application of both interventions

* Subject specific parameters that influence the effects of (the combination of) tsDCS and robotic gait training

Study description

Background summary

Spinal Cord Injury (SCI) is usually a severe injury to the pathways of the central nervous system (CNS) in the spinal cord. Depending on where the injury occurs, patients are often bound to a wheelchair or left with other impairments diminishing their quality of life, despite a heavy post injury physical rehabilitation regime. Trans-spinal direct current stimulation (tsDCS) and robotic gait therapy are two promising new techniques under investigation for the treatment of SCI. TsDCS is aiming to alter the response of the neural pathways the stimulus is applied to. The resulting alteration of neural activity in the spinal cord is hypothesized to have a positive effect on the recovery of the damaged spinal cord neurons.
Similarly, robotic gait therapy is hypothesized to have a positive effect on the cortico-spinal pathways by increasing the task specific intensity and thereby aiding activity dependent plastic in the CNS.

Study objective

The primary objective is to assess the neural short term changes, robotic gait therapy and tsDCS have on the corticospinal pathways. Thereby it has to be investigated in what kind of configuration and intensity tsDCS is most effective as well as what kind of control scheme is most effective when using more or less walking assistance during robotic walking assistance with the LOPES II exoskeleton.

Study design

The overall goal is to perform all studies as randomized double blind controlled trials.

Intervention

For each experiment in this study, subjects will receive either tsDCS or robotic therapy as an intervention. Possible is also a combination of both techniques.
tsDCS is applied to the lumbar spinal cord for a period of maximum 15 minutes. Stimulation amplitude may vary from zero to five milliamperes, with variable electrode configurations on the back of the subject by using up to five individual electrodes over which the applied current is divided.
Robotic therapy is applied using the LOPES exoskeleton. Thereby the subject is aided in his effort to execute stepping movements on a treadmill.

Study burden and risks

Both, tsDCS and robotic therapy are non-invasive. tsDCS involves the electrical stimulation of living tissue and therefore guidelines have to be followed for the safe use of the technique. Two factors which are vital in this respect are the overall current input into the tissue as well as the current density. Both

of these factors are limited by current strength and stimulation time. All in all the application of tsDCS within the established limits can considered to be safe with a minimum side effects.
During robotics therapy the subject is attached to the LOPES II exoskeleton, which is able to support the person in his effort to make stepping movements. The subject is thereby attached to the device via Velcro straps and secured by a safety harness to prevent falling. During, before and after operation all measures have been taken which ensures safe operation of the device which is supported by previous studies the LOPES I has been part of. Additional information concerning the LOPES II safety can be found in section 6.1. of C1.
In addition to the safety of both interventions alone, the combination of both interventions is not thought to result into any harmful effects.
Patient benefit is closely related to the duration and effect of the intervention. Thereby tsDCS produces an effect that may last up to several hours of the treatment but decline subsequently. In terms of robotic therapy it is not known to which extend there are longer lasting post treatment effects. Since it however merely involves an intensified movement training, it is not likely that any visible lasting abnormal will occur. Out if this reason subject benefit for both interventions will be unlikely.
In terms of group relatedness, the specific application to SCI the study depends on the participation of spinal cord injured subjects to a great extent. It is therefore vital that SCI patients will be able to participate.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

The inclusion criteria for the healthy subjects are:
at least 18 years old
good vision (on 2 m distance) ;The inclusion criteria for chronic spinal cord injured subjects are:
age > 18 years
good vision (on 2 m distance)
chronic stage: time since SCI > 12 months
clear walking impairment but able to walk independently (with support) (WISCI > 1 and SCIM > 30)
motor incomplete spinal cord injury (ASIA C or ASIA D)
a stable medical condition
Injury situated superior to the T9 vertebra

Exclusion criteria

history of skin diseases that could result in irritation of the skin underneath the electrodes
history of epilepsy or a known case of epilepsy in a first degree relative
metallic implants in the body, unrelated to the spinal cord injury, in proximity to the stimulation electrodes
metallic implants in the body, related to the spinal cord injury, below vertebrae T6
presence of cardiac pacemakers, cochlear implant or implanted brain electrodes
use of any illegal drugs in the last year
(possibility of) pregnancy
current orthopedic problems
other neurological disorders
chronic joint pain
history of cardiac conditions that interfere with physical load
history of severe depression
Stable use of anti-spasticity medication

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2015
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	LOPES II Exoskeleton _and_ 5 Channel Electrical Stimulator
Registration:	No

Ethics review

Approved WMO Date:	18-12-2014
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	30-04-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-08-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Approved WMO Date:	03-09-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-02-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-04-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	18-07-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL49561.044.14