Effects of overnight electrical stimulation on local oxygenation and muscle thickness in people with spinal cord injury

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The study will excist of two experiments. The first experiment is a two week overnight electrical stimulation program and in the second experiment subjects will be stimulated for 4 months.With these two experiments we wish to answer the following…

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

Summary

ID

NL-OMON37894

Source
ToetsingOnline

Brief title
Overnight electrical stimulation in people with spinal cord injury

Condition

- Spinal cord and nerve root disorders

Synonym
paraplegia, Spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Reade

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Electrical stimulation, Pressure sores, preventive, Spinal cord injury

Outcome measures

Primary outcome

Primary study parameters for both experiments are listed below.

Experiment 1:

Tissue saturation in gluteal area in different conditions and effect of two weeks of overnight stimulation using Near Infrared Spectroscopy (NIRS)

Oxygen uptake and blood flow in Vastus lateralis and effect of two weeks of overnight stimulation using NIRS

Usability of overnight electrical stimulation. Determined by questionnaires(PSQI, SQ-VAS, Usability questionnaire)

Experiment 2:

Thickness of gluteus maximus muscle and effect of four months of overnight stimulation, determined by CT scan

Usability of overnight electrical stimulation. Determined by questionnaires(PSQI, SQ-VAS, Usability questionnaire)

Secondary outcome

Experiment 1

Energy expenditure in rest and during electrical stimulation and effect of two

weeks of overnight stimulation using COSMED

Interface pressure while sitting compared to baseline using mFlex

Muscle fatigue, compared to baseline using load cell.

Experiment 2

Tissue saturation in gluteal area in different conditions and effect of four

months of overnight stimulation using Near Infrared Spectroscopy (NIRS)

Oxygen uptake and blood flow in Vastus lateralis and effect of four months of

overnight stimulation using NIRS

Energy expenditure in rest and during electrical stimulation and effect of four

months of overnight stimulation using COSMED

Interface pressure while sitting compared to baseline using mFlex

Study description

Background summary

One of the most prominent secondary problems following SCI is the occurrence of pressure ulcers. Computer models show that the highest stress and strain values can be found in the gluteal muscles during sitting, causing tissue damage. Furthermore, amount of affected tissue seems to increase with muscle atrophy. Changes in local blood flow characteristics also occur in persons with SCI. For example, research has shown decreased post-occlusion blood flow in persons with SCI. Atrophy of gluteal muscles, decreased blood flow and oxygenation in combination with prolonged periods of sitting cause the area right beneath the ischial tuberosities to be of high risk for developing pressure ulcers. To prevent pressure ulcers electrical stimulation might be a useful tool. Activation of glutes and muscles in upper leg could preserve or improve muscle mass and improve oxygenation of stimulated tissue.

There are several ways to apply electrical stimulation. In this study we focus

on feasability of overnight electrical stimulation using electrical stimulation shorts. Overnight electrical stimulation could be a favoured method in using electrical stimulation because daily activities are not disturbed. In addition, getting in and out of the shorts can easily be done when the subject is in bed. Therefore setting up electrical stimulation for overnight electrical stimulation has the advantage that no extra transfers are required.

We expect overnight electrical stimulation to be a feasible and convenient way of applying electrical stimulation which does not disturb spinal cord injury patients in any way. Furthermore, we expect overnight electrical stimulation to increase muscle mass of stimulated muscles and improve oxygenation in stimulated area.

For a more detailed description we refere to the introduction of the research proposal

Study objective

The study will excist of two experiments. The first experiment is a two week overnight electrical stimulation program and in the second experiment subjects will be stimulated for 4 months.With these two experiments we wish to answer the following research question.

Is overnight electrical stimulation a useful method to reduce the risk on pressure ulcers?

Specific aims of the two experiments are listed below

Experiment 1: Two week overnight stimulation program
1) Evaluate if electrical stimulation can be applied overnight without disturbing sleep
2) Determine oxygenation in the stimulated area in different conditions.
3) Determine effect of 2 weeks of overnight electrical stimulation on oxygenation in stimulated areas.

Experiment 2: Four months overnight stimulation program
1) Deteremine effects of 4 months of overnight stimulation on muscle mass in stimulated area
2) Determine effect of 4 months of overnight stimulation on pressure distribution, during sitting.
3) Establish the effects of 4 months of overnight electrical stimulation on oxygenation in stimulated area.

Study design

Desing for both experiments will be a "one group pretest - posttest" design.

Experiment 1:
will be determined prior to and directly after 2 weeks of electrical stimulation. Quality of sleep will be measured every week using questionnaires. Tissue saturation in gluteus maximus muscle, oxygen uptake and blood flow in vastus lateralis muscle, energy expenditure, muscle fatigue and interface pressure will be measured prior to the intervention, a day before onset of electrical stimulation, after two weeks of electrical stimulation and 2 weeks after ending the stimulation program.

Experiment 2:
Thickness of gluteus maximus muscle will be measured prior to and directly after the intervention. Measurements of tissue saturation in gluteus maximus muscle, oxygen uptake and blood flow in vastus lateralis muscle and energy expenditure will take place prior to the study, a day before onset of stimulation, after 2 and 4 months of overnight electrical stimulation and 2 months after ending electrical stimulation.Quality of sleep will be tested, using questionnaires, weekly for the first 4 weeks and once every 4 weeks after the first month of the program. Interface pressure and buttock dimensions will be measured weekly throughout the intervention.

Intervention

Subjects will be stimulated every night throughout the experiments (2 weeks or 4 months). The subjects will take their ES shorts and neuromuscular electrical stimulators home and subjects are asked to put on the ES shorts every night before going to bed and start electrical stimulation as they lie in bed. Stimulation program will end 8 hours after starting, however subjects are allowed to stop electrical stimulation before program is ended. Biphasic stimulation will be applied at 35Hz to achieve tetanic muscle contraction, with amplitudes of current stimulation established during setup. In this test, the subject will wear the ES-shorts and be placed in bed in a supine position. The electrical stimulation amplitude for the program is determined as the highest amplitude, with a maximum of 150 mA, which subjects do not find unpleasant or disturbing and where a muscle contraction is visible. In the second experiment every two weeks amplitude will be adjusted if needed.

Study burden and risks

Subjects will visit the lab 4 and 5 times for the short and long experiment respectively. Each visit will take approximatily 3 hours except for the first visit where shorts will be fitted an stimulation program is set as well, first visit will take 4 hours.

In these visits the oxygenation in gluteal area will be determined, therefore a

small probe will be attached under the buttocks. In addition, to determine oxygenation in vastus lateralis a cuff will be placed around the upper leg for small periods. Measurements of energy expenditure will be performed by putting on a mask. Subjects are able to breath normally during this measurement. In the short experiment subjects will have to fill out questionnaires every week. Ïn the long experiment a researcher will visit the subjects every week in order to measure interface pressure and buttock dimensions. These visits will take about 30 minutes each. In addition, in the long experiment subjects will go to the Jan van Bremen Institute twice for CT scans.

Electrical stimulation will be applied every night. Electrical stimulation cause muscle contractions, as a result of the contractions there could be movement in the limbs. In addition, electrical stimulation could be percepted as unpleasant. Therefore, electrical stimulation could disturb sleep. However, we expect overnight electrical stimulation not to be disturbing sleep. Movement of limbs will be fairly little, because stimulation parameters are not maximal. Furthermore, because of the loss of sensory in the lower limbs it is not likely that electrical stimulation will disturb the subjects. Using the electrical stimulator is safe, the stimulator will stop stimulation over a channel if contact between electrode and skin or electrode and stimulator is lost.

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

Inclusion criteria are cervical or thoracic lesions, ASIA A/B. Subjects have to be at least 1 year post injury

Exclusion criteria

Subjects with (cardio)vascular diseases, diabetes, hypercholesterol or high blood pressure will be excluded. Furthermore subjects with an intolerance to electrical stimulation, presence of pressure ulcers on ischial tuberosity area or sacrum, presence of a pacemaker or metal implants near stimulation area are excluded.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-05-2012
Enrollment:	18

Type:	Actual

Medical products/devices used

Generic name:	Electrical stimulator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-04-2012
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL39835.048.12