Acute effects of unilateral lower limb electrical stimulation induced muscle activation on peripheral vascular blood flow in SCI

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The purpose of this study is to investigate the acute effects of gluteal and hamstring ES on femoral artery blood flow, skin vascular function and energy expenditure using ES shorts as a simplistic non-invasive method of ES.

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

Summary

ID

NL-OMON43259

Source
ToetsingOnline

Brief title
Electrical stimulation and blood flow

Condition

- Spinal cord and nerve root disorders

Synonym
paraplegia, spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit

Source(s) of monetary or material Support: Buckinghamshire Healthcare NHS Trust

Intervention

Keyword: circulation, electrical stimulation, pressure sores, spinal cord injury

Outcome measures

Primary outcome

Profunda femoral artery blood flow: The profunda is a deep artery of the thigh that travels more posteriorly than the rest of the femoral artery to supply the gluteal and hamstring muscles. Using a 2-dimensional echo Doppler ultrasound device, scans of the prounda femoral artery will be collected to determine artery diameter and blood flow (BF). Measurements will be performed at baseline (rest), every 15 minutes during the 2-hour stimulation protocol 30 minutes and 1-hour post stimulation in the intervention leg. Measurements in the unstimulated control leg will be performed pre and post stimulation. All measurements will be recorded for later offline analysis using custom-designed edge detection and wall tracking software

Skin vascular function (CVC): Cutaneous blood flow will be measured on the gluteal/thigh area using laser-Doppler flowmetry (Periflux 5001, Sweden). Measurements will be performed pre, during and post stimulation in the control and intervention legs. Local skin temperature will be controlled at 33 °C using local heating units (Perimed 455, Sweden). Cutaneous vascular conductance (CVC) will be calculated as flux (AU) divided by MAP (mmHg).

Secondary outcome

Energy Expenditure: Participants will wear a facemask and energy expenditure

will be calculated based on oxygen consumption measured by open-circuit spirometry (COSMED K4b2, Rome, Italy). Mean energy expenditure without ES will be calculated during the first 10 minutes of the resting period before the start of ES. Mean energy expenditure during ES will be calculated over each block of ES during the 2-hour protocol.

Study description

Background summary

Following a spinal cord injury (SCI) there are significant changes in peripheral vascular structure and function. A decrease in conduit artery diameter (de Groot et al., 2004; de Groot et al., 2006a; de Groot et al., 2006b), increased vascular resistance (Hopman et al., 2002), reduced capillarization (Chilibeck et al., 1999) and impaired cutaneous microcirculation (Nicotra et al., 2004; Van Duijnhoven et al., 2009) are typically observed in the paralysed, inactive limbs. Collectively, such vascular changes are associated with increased risk of cardiovascular related mortality and likely contribute to frequently reported pathologies such as skin breakdown lesions (Deitrick et al., 2007) and poor wound healing. Furthermore, individuals with a SCI experience changes in body composition including an increase in adipose tissue and a significant loss in muscle mass. These changes importantly contribute to reductions in daily energy expenditure and increase the risk of obesity among individuals with SCI.

Regular muscular contractions act as a pumping mechanism to facilitate the movement of blood through the vascular network and prevent venous pooling in the lower limbs. Due to motor paralysis below the lesion, this blood pumping mechanism is no longer active. Electro-stimulation (ES) induced muscle activation is an alternative method to overcome the loss of regular voluntary muscular contractions and improve vascular health through increased regional blood flow. Indeed, various methods of ES in SCI have resulted in improved transcutaneous oxygen levels (Smit et al., 2013b; Wu et al., 2013), increase femoral artery diameters (Thijssen et al., 2006) and decreased peripheral vascular resistance (Hopman et al., 2002). Additionally, the use of ES increases circulating blood volume to the normally inactive limbs, thus increasing oxygen demand of the working muscles and potentially increasing energy expenditure. However, a majority of ES methods currently used require specialist facilities and trained staff, are labour intensive and impractical.

Specially fabricated clothing with built in electrodes may be an alternative way to administer ES without the expense and practicality issues associated with other methods of ES. For example, Smit et al have previously used partially elasticated lycra shorts with embedded surface electrodes as a way of activating the gluteal and hamstring muscles in persons with SCI. They found that an acute bout of ES lead to significant pressure relief in areas at risk of skin breakdown lesions (Smit et al., 2013a). Furthermore, the participants involved in the study stated that they would be satisfied wearing the shorts on a daily basis providing they helped ameliorate the risk factors associated with pressure ulcers. Considering that ES induced gluteal and hamstring activation has previously been shown to increase (sub)cutaneous blood flow and oxygenation (Smit et al., 2013b), other areas of the deeper vasculature may also be subject to increases in blood flow. To our knowledge, no study has measured conduit artery blood flow during an acute bout of ES in SCI individuals.

Study objective

The purpose of this study is to investigate the acute effects of gluteal and hamstring ES on femoral artery blood flow, skin vascular function and energy expenditure using ES shorts as a simplistic non-invasive method of ES.

Study design

Ten individuals with a spinal cord injury will be recruited to take part in this study. The ES intervention consists of a portable functional electrical stimulation box (Neuropro, BerkelBikes, Sint-Michielsgestel, The Netherlands) connected to a wearable garment (shorts), which will safely house the wires from the stimulator. Two built-in surface electrodes will be placed over the upper part of the gluteal muscles and 1 over the hamstring muscles of 1 leg. The surface electrodes (with conductive gel) are connected to elastic conductors, guided through the side of the shorts to the front, ensuring the participant does not sit on the wires. Stimulation will be delivered biphasically at 50Hz to induce a (visible) tetanic contraction. The current amplitude will be adjusted for each subject by increasing the current amplitude in steps of 5mA to a point that doesn*t cause discomfort or excessive muscle contractions. The stimulation protocol will consist of 3-minute blocks of gluteal and hamstring activation for a total of 2 hours. A duty cycle of 1s stimulation and 4s off will be used during the 3 minutes followed by a rest period of 16 minutes. The average current amplitude using this stimulation protocol has been 94±13 mA, ranging from 70 to 115 mA, in our previous studies. The individuals will remain in a supine position for the duration of the protocol.

Intervention

The ES intervention consists of a portable functional electrical stimulation

box (Neuropro, BerkelBikes, Sint-Michielsgestel, The Netherlands) connected to a wearable garment (shorts), which will safely house the wires from the stimulator. Two built-in surface electrodes will be placed over the upper part of the gluteal muscles and 1 over the hamstring muscles of 1 leg. The surface electrodes (with conductive gel) are connected to elastic conductors, guided through the side of the shorts to the front, ensuring the participant does not sit on the wires. Stimulation will be delivered biphasically at 50Hz to induce a (visible) tetanic contraction. The current amplitude will be adjusted for each subject by increasing the current amplitude in steps of 5mA to a point that doesn*t cause discomfort or excessive muscle contractions. The stimulation protocol will consist of 3-minute blocks of gluteal and hamstring activation for a total of 2 hours. A duty cycle of 1s stimulation and 4s off will be used during the 3 minutes followed by a rest period of 16 minutes. The average current amplitude using this stimulation protocol has been 94±13 mA, ranging from 70 to 115 mA, in our previous studies. The individuals will remain in a supine position for the duration of the protocol.

Study burden and risks

The paralyzed buttock and leg muscles of the participants will be activated, which does not evoke a marked burden or any discomfort. A minor risk is that the skin under the electrodes may be lightly irritated, but this will disappear quickly. The experiments will take 3 hours in total.

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

* Age 18-75 years
* ASIA Impairment Scale A-B with intact reflex arcs (i.e. spastic paralysis)
* Lesion level * Time since injury >6 months
* Able to tolerate stimulation (i.e. no autonomic dysreflexia induced)

Exclusion criteria

* An intolerance to or contraindication for electrical stimulation
* A history of severe autonomic dysreflexia or severe cognitive or communicative disorders
* A flaccid paralysis or areflexia

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2016
Enrollment:	10

Type:	Anticipated

Ethics review

Approved WMO Date:	20-10-2016
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	NL59052.048.16