Sitting pressure reduction induced by electrical stimulation during daily life in people with spinal cord injuries .

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31979

Source
ToetsingOnline

Brief title
Sitting pressure reduction using electrical stimulation

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
paralysis, spinal cord injury

Health condition

dwarslaesie

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: electrical stimulation, pressure sores, spinal cord injury, wheelchair users

Outcome measures

Primary outcome

Sitting pressure distribution and user friendliness of the electrical

stimulation method.

Secondary outcome

not applicable

Study description

Background summary

Pressures sores are mainly caused by pressure, shear forces, friction, or a combination of these and usually occur over bony prominences such as the ischial tuberosity. Wheelchair users with spinal cord injuries (SCI) sit for long periods, resulting in long lasting high pressures of the tissue, which may be even higher due to atrophy of the paralyzed muscles, leading to higher local peak pressures. In addition, blood flow is reduced below the lesion due to a loss of capillary network, failure of the skeletal muscle pump mechanism, drop in blood pressure and occlusion of blood vessels.
Several methods have been developed to prevent pressure sores by improving the sitting pressure distribution, e.g. special cushions and protective behavior (e.g., lifting). Although the cushions can improve sitting pressure distribution, they do not reduce muscle atrophy or improve blood flow. Protective behavior has no unambiguous effect on the development of pressure sores. Apparently, these methods may not be completely adequate, indicating a need for additional methods.
A method to accomplish a better sitting pressure distribution, reduced muscle atrophy, and increased blood flow is by activating the gluteal muscles using electrical stimulation (ES), temporarily changing the buttock shape and concomitantly the sitting pressure distribution. Until now, not much is known

about this method.

Study objective

The main purpose of this study is to evaluate the effects of surface electrical stimulation of the gluteal and hamstring muscles on sitting pressure under the buttocks during daily life (3 hours). A second purpose is to compare the effects of only gluteal muscle activation with a combined gluteal-hamstring muscle stimulation.

Study design

Intervention study, no control group.

Intervention

Activation of the paralyzed gluteal and hamstring muscles by electrical stimulation.

Study burden and risks

The extra physical burden on the subjects is minimal. The paralyzed muscles will contract but this will have hardly any effect on the subject. He/she will be able to perform daily activities as usual. The time needed for this project is limited to 14 hours for each subject, divided ovcer 2 sessions. There is a small chance that the subjects find the stimulation painful. In that case, the current will be decreased immediately. In about 10% of the population, electrical stimulation may induce autonomic dysreflexia (high blood pressure). This will be determined in a screening session. If this occurs, subjects will be excluded from the experiments. The stimulation may induce some redness of the skin, but this will disappear after a few hours.

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

- spinal cord injury
- age: 18-70 yrs.
- intact patella tendon reflex (upper motor neuron lesion)
- intact mm. gluteï maximi en hamstrings

Exclusion criteria

- presence of a pressure sore on buttocks
- flaccid paralysis (no muscle activation by surface electrical stimulation possible)
- occurrence of autonomic dysreflexia with electrical stimulation

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2008
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	26-05-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL22712.029.08