Daily electrical stimulation to prevent recurring pressure ulcers in patients with a spinal cord injury compared to usual care

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To investigate whether daily electrical stimulation of gluteal and hamstring muscles combined with usual care is more effective than only usual in individuals with chronic SCI who often have PU*s and/or are at high of recurring PU*s regarding: 1)…

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

Summary

ID

NL-OMON54487

Source
ToetsingOnline

Brief title
SCI PREVOLT
Daily electrical stimulation to prevent pressure ulcers

Condition

- Other condition
- Spinal cord and nerve root disorders

Synonym
Bedsores, Pressure ulcers

Health condition

dwarslaesie, decubitus

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Daily, Electrical Stimulation, Pressure Ulcers, Prevention

Outcome measures

Primary outcome

Primary outcome parameter is PU incidence during one year.

Secondary outcome

Secondary outcome parameters are PU risk factors (interface pressure distribution, local circulation, muscle size), participation, and health-related quality of life. Other outcome parameters are societal as well as healthcare cost, process evaluation and the usability of the electrical stimulation system.

Study description

Background summary

Pressure ulcers (PU*s) are among the most prevalent complication in individuals with spinal cord injury (SCI), resulting from sitting for extended periods, disuse atrophy, increased sitting pressure, and reduced circulation. PU*s can limit mobility, independence and decrease quality of life, are an important cause of re-hospitalization, can lead to osteomyelitis, sepsis and even death. Compared with usual care, activation of paralyzed muscles using electrical stimulation has been shown to markedly increase paralyzed muscle mass and improve circulation of skin and muscle, and might therefore be a useful method to reduce PU incidence.

Study objective

To investigate whether daily electrical stimulation of gluteal and hamstring muscles combined with usual care is more effective than only usual in individuals with chronic SCI who often have PU*s and/or are at high of recurring PU*s regarding: 1) reducing PU incidence; 2) improving a) factors related to PU risk: interface- pressure distribution, local circulation, and muscle size; b) mobility, participation, and quality of life.
The 3rd objective is to evaluate the association between risk factors (sitting pressure distribution, blood circulation, muscle size) and PU development/incidence. The last three objectives are: 4) To determine the cost-effectiveness of this method compared with usual care alone; 5) To investigate facilitators and barriers for the implementation and sustainability of daily electrical stimulation within usual care; 6) To evaluate the long-term usability and user-friendliness of this electrical stimulation system.

Study design

A prospective multicenter RCT design will be used with an economic and process evaluation alongside. Follow-up will be 12 months.

Intervention

In addition to usual care, the intervention group will receive surface electrical stimulation of the gluteal and hamstring muscles during one year (>1 hr/day, >4 days/wk).

Study burden and risks

Participants are asked to visit a rehabilitation center five times in 12 months. One appointment will be for checking whether the participant is eligible for the study. The other 4 appointments consist of measuring blood flow, muscle mass and siting pressure distribution. This will take about 90-150 minutes in total. To measure the PU incidence the experimental group and the control group will get a notification or email every 2 weeks. To ask whether there is a new PU or not. In addition to this, a picture of the gluteal area is taken and sent every month to evaluate the sacral or ischial tuberosity*s region. Participants will be asked to fill in an online questionnaire at baseline and every 3 months.
Possible benefits of participating in this study are a lower PU incidence, improved muscle mass, improved blood flow and a better sitting pressure distribution due to electrical stimulation. Next to that participants will get a 2 weeks wound check-up for free which can create more awareness for wound prevention.

Contacts

Public
Vrije Universiteit

V.d. Boechorststraat 7-9
Amsterdam 1081 BT
NL
Scientific
Vrije Universiteit

V.d. Boechorststraat 7-9
Amsterdam 1081 BT
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria for the objective:
- Individuals (Male/Female) either a complete or incomplete chronic SCI*
- Age 18 and older
- Intact gluteal and hamstring muscles.**
- Individuals within a 5 year time since injury and a minimal incidence of 1 PU or more***
- Individuals with a more than 5 year time since injury and a minimal incidence of 1 PU or more within the last 5 years.***
- Can lay in a prone position for at least 10 minutes (safety neck, comfortable, not compromising breathing and possibly due to contractures)
*In this study, a chronic SCI is defined as follow: *Every individual with an

SCI who is discharged from a rehabilitation center whether this is after 3, 6 or 12 months of first inpatient rehabilitation.*
** Potential participant who underwent flap surgery or another kind of plastic surgery can still be included if they got a good muscle contraction.
***Only PU*s within the (Category 2-4) In the sacral or ischial tuberosity*s region according to the European pressure Ulcer Advisory Panel.(28).

Exclusion criteria

- current PU*s in the gluteal or sacral area
- flaccid paralysis (areflexia)
- a history of severe autonomic dysreflexia
- Insufficient mastery of the Dutch language (speaking and reading)
- severe cognitive or communicative disorders
- intolerance to or contra indication for electrical stimulation (cancer, pregnant)
- recent or current participation in an electrical stimulation-induced exercise program
- participation will be excluded if they participated in an ES study or ES therapy 6 months prior to the study
- severe psychiatric illness or disorders (to the discretion of the treating rehabilitation physician).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-11-2023

Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Transcutaneous Electrical nerve stimulator: EMP4 ECO+
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-03-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-08-2023
Application type:	Amendment
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

ID: 21504

Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74020.029.20
Other	NL9469