Thermoregulation in patients with spinal cord injury and cold sensations, an explorative pilot-study

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To investigate whether SCI patients with regular complaints of cold sensations in daily life have more impaired thermoregulatory responses to changes in environmental temperature compared to SCI patients who do not have these cold sensations in...

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

Summary

ID

NL-OMON45840

Source
ToetsingOnline

Brief title
Cold sensations in spinal cord injury

Condition

- Spinal cord and nerve root disorders

Synonym
palsy, paralysis, paraplegia, spinal cord injury, tetraplegia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cold sensations, Core body temperature, Skin temperature, Spinal cord injury

Outcome measures

Primary outcome

Between group differences in change in core body and skin temperature during cold exposure.

Secondary outcome

Secondary study parameters are the change in core body and skin temperature during warmer conditions.

Also, differences in baseline parameters: blood pressure, heart rate, fat percentage, physical activity levels, life satisfaction and autonomic functioning.

Study description

Background summary

Cold sensations are a common complaint in patients with spinal cord injury (SCI) and have a negative effect on quality of life and daily activities. However, the pathophysiology of these sensations and whether patients who experience these sensations have more impaired thermoregulatory responses compared to patients who do not, is currently unknown.

Study objective

To investigate whether SCI patients with regular complaints of cold sensations in daily life have more impaired thermoregulatory responses to changes in environmental temperature compared to SCI patients who do not have these cold sensations in daily life. We hypothesize that patients with regular complaints of cold sensations have more impaired thermoregulatory responses to changes in environmental temperature. We expect that they are not able to stabilize their core body temperature during changes in environmental temperature and that skin temperature will remain stable. Moreover, we expect that patients without these

complaints in daily life will be able to keep their core body temperature stable by varying their skin temperature (due to better vasomotor control) under the different environmental temperatures.

Study design

This is an observational study of two SCI patient groups, one with and one without regular complaints of cold sensations. Both groups will be exposed to a cold environment (18-19°C) for 120 minutes and subsequently to a warmer environment (24°C) for 60 minutes. During these interventions, core body and skin temperature, thermal sensation, pain score, heart rate and blood pressure will be measured.

Study burden and risks

Patients will report to the laboratory once for the measurements (4,5hr). Beforehand, they will fill in the questionnaires (0,5hr). Cold exposure and measuring blood pressure can cause some discomfort. For safety, body temperature will be checked regularly and the measurements will be aborted when temperature drops to or below 35°C or increase to or above 38.5°C. A physician can be contacted in case of emergency. Due to the changes in physiological processes/thermoregulation in SCI, a comparison with healthy control subjects would not answer our research question and inclusion of a patient-control group is necessary.

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

* SCI patient of the Sint Maartenskliniek, Nijmegen
* Lesion at or above T6
* Subjects in the chronic phase of SCI (>6 months)
* Age between 18-65 years old
* Complaints of cold sensations on on at least half of the days throughout the year with a NRS of 4 or higher of limitations on activity or participation level (for half of the participants, not for the patient-control group_

Exclusion criteria

* Recent change in medication affecting (neuropathic) pain (<3 months)
* Fever on the day of measurement or the use of paracetamol the day of the measurements
* Pacemaker, implantable baclofen pump, or other implanted electrical devices
* M. Crohn, colitis ulcerosa or other gastro-intestinal disease
* Body weight < 36,5 kg
* MRI scan planned within 7 days of measurements
* Medical history of gastro-intestinal surgery

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2020
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL68038.091.18

Study results