Changes in core body temperature during exercise in the morning or evening and their impact upon the circadian rhythm in core body temperature in SCI

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON32921

Source
ToetsingOnline

Brief title
Core body temperature in SCI during exercise and 24-h registration

Condition

- Other condition

Synonym
spinal cord injury

Health condition

dwarslaesie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: core body temperature, exercise, spinal cord injury, thermoregulation

Outcome measures

Primary outcome

The following measurements and assessments will be done:

1) core body temperatue during 24 hrs (telemetry pill)

2) skin temperature (above and below the level of lesion)

3) activity monitoring (sensewear)

4) venous blood withdrawal (before and after exercise for assessment of lactate

and plasma sodium concentrations)

5) heart frequency

Secondary outcome

n.a.

Study description

Background summary

Thermoregulation is importantly impacted in individuals with spinal cord injury (SCI). When exposed to a thermophysiological stimulus, such as extreme heat or cold, people with a SCI adapt differently than able-bodied people, eventually resulting in a larger increase or decrease in the core body temperature. This thermoregulatory dysfunction is primarily due to a decrease or even a loss of neural activity from the regions below the level of the lesion to the

thermoregulatory centre (21) as well as a disruption of both vasomotor control and sweating capacity below the level of lesion (12). Consequently, paraplegics and tetraplegics show a higher risk to heat illness when exposed to heat or while exercising (2, 9), but also have problems with their thermoregulatory functions in daily living leading to a clinically frequently reported *cold legs*. Currently, little is known about the circadian rhythm of the core body temperature in SCI, but also the responses and recovery of the core body temperature to exercise are unknown. In addition, due to possible fluctuations of the temperature throughout the day (circadian rhythms), the exercise-induced responses of the core body temperature may vary dependent on the timing of exercise.

Study objective

Our main aim is to describe the 24-h circadian rhythm of skin and core body temperature in people with SCI and the change in skin and core body temperature during and after an exercise bout in SCI and controls. Secondly, we wish to examine differences in the exercise-induced changes in skin and core body temperature in SCI and controls when exercise is performed at different moments of the day (8 am and 8 pm).

Study design

Observational study

Study burden and risks

The intake of this telemetry pill is non-invasive and not dangerous as it can be swallowed similarly as any medication pill. Our department has extensive experience with this telemetry system and has been used in previous study protocols which were approved by the ethics committee (CMO-nr 2007/147, 2007/262). An ingestion of this pill will also cause no harm to the body and its function due to the sophisticated elaboration of protection to its surrounding. The pill has been proved to be reliable and valid for measuring core body temperature at rest and during exercise, and is now being used and registered at the *Food and Drug Administration (FDA)* for 19 years. The pill telemetry system has also been used in SCI subjects in previous studies without any negative side effect. Important advantages of this system is that it is non-invasive, valid, does not have the sanitary problems when using different techniques (such as rectal probes) and can be used without noticing by the subject. From the >35,000 pills that have been distributed, no negative incidents have been reported. In addition, the Department of Physiology has experience with >200 subjects that have used the pill for 1 or multiple day core body temperature measurements. So far, we have not noticed any negative impact of using the pill in any of the participants.

The other techniques used in this study (exercise tests, activity monitor, skin temperature, heart rate recording) are all techniques that have been used for several years at the Department of Physiology. None of these measuring techniques are invasive, painful or possible dangerous for the subject. Using these techniques will also not influence their daily living.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-noord 21
6525 EZ Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-noord 21
6525 EZ Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Spinal cord injury:
- complete thoracic or cervical spinal cord lesion
- ability to perform arm-crank exercise;Controls:
- healthy

Exclusion criteria

All subjects:
- cardiovascular diseases
- medication known to interfere with the thermoregulation
- To prevent problems with using the telemetry pill we use the following exclusion criteria:
1. obstructive disease of the gastro-intestinal tract, including diverticulitis and inflammatory bowel disease
2. previous gastrointestinal surgery, except cholecystectomy and appendectomy
3. MRI during the period that the CorTemptm sensor is within the body (e.g. 1 day preceding the 7-hills run, the day of the 7-hills run and 2 days after the 7-hills run)
4. subject having a cardiac pacemaker or other implanted electromedical device.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2008
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-10-2008
Application type:	First submission
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	NL24849.091.08