Circadian rhythm in core body temperature and melatonin-levels in spinal cord injury

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34408

Source
ToetsingOnline

Brief title
Core body temperature and melatonin in SCI

Condition

- Hypothalamus and pituitary gland disorders
- Spinal cord and nerve root disorders

Synonym
sleep disorder, Spinal cord injury

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: Circadian rhythm, Core body temperature, Melatonine, Spinal cord injury

Outcome measures

Primary outcome

Melatonin and cortisol levels (using saliva-samples)

Secondary outcome

Core body temperature during 24 hrs (telemetry pill)

Skin temperature (above and below the level of lesion)

Study description

Background summary

Core body temperature (CBT) shows circadian rhythmicity with a nadir in the morning between 4-6 am and a peak 1-4 hours before bedtime. A normal circadian rhythm is prerequisite for a normal sleep pattern. Individuals with a spinal cord injury demonstrate a pronounced disturbance in the circadian rhythm of CBT, whilst this group also frequently reports sleeping problems. The mechanism behind the altered CBT may relate to the release of melatonin, a hormone that contributes to a normal sleeping pattern and is produced via neural pathways that include the central nervous system. No previous study performed a comprehensive assessment of the release of melatonin and cortisol in spinal cord-injured individuals and link the endocrine function to the rhythmicity of CBT.

Study objective

Our main aim is to describe the 24-h circadian rhythm of skin and core body temperature in people with SCI and examine whether changes in melatonin and/or cortisol relate to the altered circadian rhythm in core body temperature recently described in group.

Study design

Observational study

Study burden and risks

Subjects will wear 8 temperature sensors (4 upper limbs and 4 lower limbs), ingest a pill to record core body temperature, wear a Sensewear to record physical activity, and wear a cuff around upper arm for a 24-h blood pressure recording. In addition, from 6 till 12 PM, subjects are instructed to take a salivary sample for later analysis of melatonin and cortisol. Experiments will be performed at home during their normal daily activities. Researchers will visit participants at home for instruction and instrumentation in the morning before the test to minimize the burden for the participants.

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, 2008/196, 2008/227, 2009/006, 2009/096, 2009/274, 2010/157). 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 21 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 >500 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 (activity monitor, skin temperature, blood pressure assessment) are 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.

Participants will be instructed to take hourly salivary samples between 6 and 12 PM for assessment of melatonin and cortisol levels. After a short and simple explanation, participants will be able to take this salivary sample, which will be stored for later analysis in our laboratory. This technique is non-invasive and has no risk for complications. Our collaborators (Prof. G. Atkinson and Dr. H. Jones, Liverpool John Moores University, United Kingdom) have extensive experience with this technique (when performed by participants themselves) and will be involved in setting up and performing this experiment.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Postbus 9101
6500 HB 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
18-50 years of age

Exclusion criteria

Obstructive disease of the gastro-intestinal tract, including diverticulitis and inflammatory bowel disease, or previous gastrointestinal surgery, except cholecystectomy and appendectomy.
Subjects that will undergo a MRI-scan within 2 days after one of the testing days, or subjects with a cardiac pacemaker or other implanted electromedical devices

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	15-10-2010
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	NL33691.091.10