The relation between sleep characteristics and glycemic control in patients with type 1 diabetes mellitus (with a special focus on role of the skin temperature regulation in relation to sleep)

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To investigate the association between sleep characteristics and glucoregulation (HbA1c) and sleep in patients with DM1.- Is there a relation between sleep characteristics and the quality of glycemic control in patients with DM1*?To compare the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON33263

Source
ToetsingOnline

Brief title
Sleep characteristics and glycemic control

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes, Glucose Metabolism Disorders

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Beurs van het Diabetes Fonds

Intervention

Keyword: Diabetes Mellitus type 1, Glucoregulation, Slaap characteristics, Thermoregulation

Outcome measures

Primary outcome

Glucose levels (only DM1) by subcutaneous, continuous glucosesensor (Only in

diabetic

patients)

Body temperature recordings:

- Registration of distal and proximal skin temperature by iButton

- Core body temperature measured by JONAH-capsule

Sleep-wake cycle by Actigraphy

Subjective sleep and daytime sleepiness by sleep questionnaires and SART

Quantitative Sensory testing by the modified Toronto clinical neuropathy score

(mTCNs) and the Thermal Sensory Analyzer (TSA)

Objective sleep characteristics by Polysomnography (PSG)

Secondary outcome

None

Study description

Background summary

Type 1 diabetes mellitus (DM1) is caused by destruction of pancreatic β-cells which results in absolute insulin deficiency. Intensive treatment is essential to obtain optimal glucoregulation, because diabetic complications depend on the degree of long term hyperglycemia. However, glucoregulation can not be normalized in patients with DM1. This is reflected in relatively large variations in blood glucose levels and relatively high HbA1c levels compared to healthy subjects.
There is a relation between sleep characteristics and metabolic regulation. Decreased sleep duration and/or quality can induce glucose intolerance and a reduction in the acute insulin response to glucose in healthy volunteers Decreased sleep quality is also a significant predictor of HbA1c values in patients with DM2. For instance, disruption of slow wave sleep (SWS) can be responsible for the adverse effects of sleep on glucose metabolism. There is only limited knowledge of sleep patterns in patients with DM1. A recent study provided evidence for an altered sleep architecture in patients with DM1 under non-hypoglycaemic conditions. These patients showed a tendency toward less deep sleep, with decreased amounts of slow wave sleep (SWS) during the first half of the night.
In healthy controls, there is a relationship between sleep and the thermoregulatory system. The circadian rhythms of core body temperature (CBT) and skin temperature show a day-night rhythm that is linked to the sleep-wake cycle. The circadian rhythm of the CBT is characterized by a relatively low temperature throughout the nocturnal sleeping period and a relatively high temperature during the daytime waking period. The decrease in CBT in the evening is achieved by allowing heat to be lost. The underlying mechanism is an increase in skin blood flow caused by reduction of hypothalamically regulated sympathetic cutaneous vasoconstrictor tone, causing skin warming and dissipation of body heat. In normal sleeping conditions, skin temperature in people is therefore higher during the sleep, a rhythm that is the inverse of that of the CBT.
It has been proposed that autonomic changes in skin temperature modulate the neuronal activity of thermosensitive neurons in the preoptic area/ anterior hypothalamus (POAH), which in turn regulate vigilance and sleepiness. A relatively high temperature of the distal skin (hands and feet) compared to that of the proximal skin proved to be related to the process of falling asleep; in other words a higher *distal-to-proximal gradient* (DPG) predicts

sleep onset. Experiments applying controlled skin warming indicate that both proximal and distal skin temperature variations within the comfortable range causally affect sleep. Decreased CBT and increased skin temperature is associated with shortened sleep onset latency, decreased body movement during sleep and an increase in stage 3 of the non-REM (NREM) sleep. These findings indicate that the body temperature is a crucial factor affecting SWS. An impaired ability to lose heat from the periphery is associated with sleep onset insomnia.
These findings may be of particular relevance for patients with diabetes because distal thermoregulation is impaired during sleep in patients with DM, even in patients without clinical evidence of polyneuropathy. Polyneuropathy, probably the most common complication of longstanding DM [38], is likely to aggravate this problem. On the one hand sensory nerve damage will impair the afferent information on skin temperature to hypothalamic areas involved in thermoregulation and sleep regulation. On the other hand, visceromotor nerve damage will impair the ability to control both vasomotor and sudomotor tone, attenuating the ability to control skin temperature.

If patients with DM1 indeed have an altered skin temperature regulation before and during sleep, this could disturb their sleep characteristics, which in turn have an impact on glucoregulation. A vicious cycle may well ensue.

Study objective

To investigate the association between sleep characteristics and glucoregulation (HbA1c) and sleep in patients with DM1.
- Is there a relation between sleep characteristics and the quality of glycemic
control in patients with DM1*?

To compare the relation between core and skin temperature and sleep characteristics in patients with DM1 and healthy controls.
- *Is the relation between core and skin temperature and sleep characteristics altered in patients with DM1*?

To determine whether diabetic polyneuropathy alters the relation between skin temperature and sleep characteristics.
- *Are the core and/or skin temperature during sleep altered by diabetic polyneuropathy in patients with DM1*?

Study design

The study consists of 1 study day.
In addition, measurements will be done at home.

•Assessment for polyneuropathy will include quantitative sensory testing using

the "Thermal Sensory Analyzer" (TSA) and the modified Toronto Clinical Neuropathy score (mTCNs) will be performed.

- Subjective sleep quality/sleepiness by sleep questionnaires and SART

•After the assessment of the absence/presence and severity of the neuropathy the 9 iButton Temperature monitors will be affixed by the researcher on standardized places on the body (see Appendix D) to measure the distal and proximal skin temperatures. The iButtons will be worn for at least 3 days (72 hours). The subjects will be instructed to keep the devices attached throughout the study period, except during bathing and swimming.

•For the measurement of the CBT the patients and healthy controls will ingest a JONAH capsule at home. They will be asked to swallow the Jonah-capsule at home at 4 p.m. After swallowing the capsule they will be asked to eat and drink only products of ± 37 degrees Celsius. Participants will be allowed to consume the standard meal and drinks provided by us which only consist of only food and drinks with fixed temperature, the 37 degrees.

•The patients and healthy controls will be asked to wear an Actiwatch during 7 days, which will be measure the activity and movements during the day and night and the sleep-wake ratio. The subjects will be requested to maintain a diary for the period they wear the Actiwatch. They will be asked to record the date, general activity, start and end time of the activity, whether they were outside, inside or both during the activity and the exact times the devices will removed for bathing or other activities. (Appendix G)

•Only the DM1 patients will be asked to wear a subcutaneous glucose sensor at home during 5 days

•At the end of the study we will select two subgroups of 10 patients with DM, with extremes in PSQI scores ,who will underwent a polysomnography (PSG) to assess the relation between glucoregulation and thermoregulation with the objective sleep parameters.

Study burden and risks

•Assessment for polyneuropathy will include quantitative sensory testing using the "Thermal Sensory Analyzer" (TSA) and the modified Toronto Clinical Neuropathy score (mTCNs) will be performed.

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he subjects will be asked to visit our hospital (duration about 4 hours). In addition, measurements will be done at home.

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

Type 1 diabetes mellitus or healthy control
Infomed consent
Age > 18 and < 60 years
BMI 20-27 kg/m2

Exclusion criteria

Peripheral vascular disease or findings suggestive of peripheral vascular disease on examination (reduced or unobtainable pulses in the feet)
Pain caused by diabetic polyneuropathy
Psychiatric disorder and/or use of antipsychotic or antidepressant drugs
Working on night shifts (last 3 months)
Pregnancy
comorbidity that influence microvascular or thermoregulatory function
Hypertension (>140/90 mmHg)
Use of medication known to affect glucose metabolism (e.g. prednison)
Chronic use of sleep medication and/or melatonin
Medication that influences temperature regulation (e.g. paracetamol, aspirin)
Presence of a medical disorder (other than DM) known to be associated with neuropathy
Caffeine-, Nicotine-, Alcohol- abuse
Use of soft-, harddrugs

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:	Will not start
Enrollment:	128
Type:	Actual

Ethics review

Approved WMO

Date:	12-03-2010
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL28975.058.09

Study results

Date completed: 06-03-2014

Summary results
Trial never started