Sleep duration and - quality in patients with diabetes mellitus type 1

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• To determine the sleep pattern in patients with DM1 with validated questionnaires with a special focus on sleep duration, - quality and daytime sleepiness. • To investigate the association between sleep parameters and glucoregulation (HbA1c), we...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON33502

Source
ToetsingOnline

Brief title
Sleep in patients with DM1

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: Ministerie van OC&W,Beurs Diabetes Fonds

Intervention

Keyword: Diabetes mellitus type 1, Glucoregulation, Sleep architecture

Outcome measures

Primary outcome

• Subjective sleep duration and -quality

• Sleep efficiency

• HbA1c

• Daytime sleepiness

• Vigilance

• Risk for sleeping disturbances, i.e. restless legs syndrome, sleep apnea

Secondary outcome

nvt

Study description

Background summary

Type 1 diabetes mellitus (DM1) is due to destruction due of pancreatic β-cell which results in absolute insulin deficiency. Intensive treatment is essential in DM1 for optimal glucoregulation, because the complications are determined by the degree of long term hyperglycemia. Although novel treatment strategies, including more physiological insulin replacement therapies have been developed, glucoregulation can still 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 are unexpected variations in glucoregulation in these patients on a day to day basis.
In healthy individuals, plasma glucose homeostasis results from a tightly controlled balance between glucose production and glucose utilization, in which variations in insulin secretion play a key role. Normal glucose regulation shows a 24h circadian rhythmicity with variations in insulin secretion. In contrast, DM1 patients cannot compensate these variations in glucose tolerance by subtle changes in endogenous insulin secretion.

Increasing evidence exists for an important role of sleep in diurnal variations in glucose metabolism. Recently, attention has been focussed on the pathofysiological effects of sleep loss on glucose metabolism and endocrine function. Sleep loss and decreased quality of sleep impair glucose tolerance and insulin sensitivity, even in healthy individuals.

A recent study in patients with DM1 demonstrated decreased sleep quality compared to healthy controls and also complaints of fatigue and numbness were more seen in patients with DM1. We postulate that disturbed sleep duration and/or - quality in an important physiological determinant of glucoregulation in DM1. If patients with DM1 have an altered sleep duration and/or -quality , sleep could be one of the important physiological determinants of glucoregulation in DM1.

Study objective

• To determine the sleep pattern in patients with DM1 with validated questionnaires with a special focus on sleep duration, - quality and daytime sleepiness.

• To investigate the association between sleep parameters and glucoregulation (HbA1c), we will compare:
* Moderate/poor controlled patients (HbA1c > 7.5 % with/without organ damage) vs. well-controlled patients (HbA1c < 7.5% without organ damage)
* Well-controlled patients (HbA1c < 7.5% without organ damage) vs. healthy controls

• To determine vigilance during the day we will perform two Sustained Attention to Response Task (SART)

Study design

All patients who visit the DM outpatient clinic of the LUMC and meet the inclusion criteria will be asked to participate in this study. Subjects will be given oral explanation about the study by the investigator. When they give their informed consent, they will be asked to fill out the questionnaires about their habitual sleep duration, - quality and the existence of a possible sleeping disorder. Consequently, we will perform twice a Sustained Attention to Response Task (SART). In this test, participants are asked to respond to numbers on a computer screen during 4 minutes to test their vigilance.

We will contact the well-controlled patients with DM1 and ask them to identify someone in their group of acquaintances as a control who will fill out the questionnaires. Controls will be targeted to be of the same sex, around the same age and having about the same BMI as the patient, and not suffering from

DM. These controls will be invited to come to our hospital to fill out the questionnaires and to perform twice a SART to test their vigilance.

Study burden and risks

The subjects will be asked to fill out 3 questionnaires about their habitual sleep duration, - quality and the existence of a possible sleeping disorder. Consequently, they are asked to perform twice a Sustained Attention to Response Task. The study will take appoximately 3 hours.

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

Informed consent
HbA1c < 7.5 %
Age >18 and <60 years

Exclusion criteria

Unable to read or write Dutch
Working on night shifts
Pregnancy
Psychiatric disorders and/or use of antipsychotic or antidepressant drugs at present or in the past
Recent participation in other research projects within the last 3 months or participation in 2 or more projects in one year

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):	04-09-2009
Enrollment:	800
Type:	Actual

Ethics review

Approved WMO

Date:	04-08-2009

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	NL28301.058.09