Neuroendocrine consequences of sleep-disturbances in type 2 diabetes patients with and without depression

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The objective of this study is to investigate:1) the prevalence of insomnia in patients with T2D with and without depression2) whether insomnia in patients with T2D with and without depression, is associated with increased levens of HbA1C3) whether...

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

Summary

ID

NL-OMON37594

Source
ToetsingOnline

Brief title
Depression, Diabetes and Insomnia

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Mood disorders and disturbances NEC

Synonym
Insomnia Diabetes Depression

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Fonds Psychische

Gezondheid en Diabetes Fonds

Intervention

Keyword: Cortisol, Depression, Diabetes, Insomnia

Outcome measures

Primary outcome

HbA1C

Secondary outcome

n.a.

Study description

Background summary

Depression and Diabetes are common disorders with a high impact on public health. The relationship between depression and diabetes is complex, depresion is asociated with increased risk of diabetes onset and depression is more prevalent in patients with diabetes. Depression is associated with worse glyceamic control in patients with diabetes, and also with increased risk of diabetes complications and mortality. However, the pathophysiological mechanism that may explain link is still unclear. Insomnia, which is prevalent in about 70% of patients suffering from depression, and persists in about 25% after remission of depression, negatively influences glycaemic control and insulin sensitivity in diabetes, supposedly through the associated misalignment of circadian variation in glucocorticoids and melatonin. Along this line of reasoning, we hypothesize that the negative effects of depression on diabetes are partly mediated by sleep problems and the underlying misalignment of the circadian rythmicity of cortisol. This hypothesis has never been tested before.

Study objective

The objective of this study is to investigate:
1) the prevalence of insomnia in patients with T2D with and without depression
2) whether insomnia in patients with T2D with and without depression, is associated with increased levens of HbA1C
3) whether the presumed association between insomnia and increased HbA1C is mediated by circadian misalignment of cortisol
Knowledge on the neuro-endocrinological mechanism underlying the

depression-diabetes relationship, can be used directly to develop more *tailor-made* treatment programs for comorbid depression, such as Bright Light Therapy, which can be used to reduce both the clinical syndrome as well as the associated neuro-endocrine deregulation.

Study design

cross-sectional observational study

Study burden and risks

No risks associated with the study. 1 extra visit to the hospital, with max 2 to 3 hrs questionnaires, 1 venapunction 3 x 4 ml, wrist actomter during 1 week, sleepdiary during 1 week, 1 day saliva monsters. No individual benefit apart from 15 euro check and travel expenses. Benefit for the patient group: develop more *tailor-made* treatment programs for comorbid depression, such as Bright Light Therapy, which can be used to reduce both the clinical syndrome as well as the associated neuro-endocrine deregulation.

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

Confirmed type-2-diabetes, 18- years and over

Exclusion criteria

Severe substance abuse or dependence, severe language barrier, psychosis, acute suicidality

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):	01-07-2012
Enrollment:	220
Type:	Actual

Ethics review

Approved WMO

Date:	18-07-2012
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL40324.029.12