Influence of antidepressant use on glucose homeostasis: a retrospective follow-up study

Published: 26-02-2007
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The study objective is the assessment of influence on glucose homeostasis as a consequence of starting switching, discontinuing or doses changes with antidepressants in a population of diabetic patients.

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

Summary

ID

NL-OMON30218

Source
ToetsingOnline

Brief title
AD-GLUCHOM-STUDY

Condition

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

Synonym
depressive disorder, Diabetes Mellitus, hyperglyceamia

Research involving
Human

Sponsors and support

Primary sponsor: Maaslandziekenhuis
Source(s) of monetary or material Support: Afdeling Klinische Farmacie

Maaslandziekenhuis

Intervention

Keyword: Antidepressants, Diabetes Mellitus, Glucose homeostasis

Outcome measures

Primary outcome

The primary study parameter is starting, swithing or discontinuing a antidepressant or having a dose change with an antidepressant.

The primary outcome is defined as changes in insulin and/or oral antidiabetic use in the period of 182 days after intervention compared to the period of 30 days prior to intervention.

Secondary outcome

Secundary study outcomes are changes in glucose glucose, HbA1, LDL, HDL and triglycerides measured during the first diabetes laboratory investigation after index date compared with the diabetes laboratory investigation prior to index date.

Study description

Background summary

Diabetes Mellitus is a serious chronic disease characterized by hyperglycemia. Long-term microvascular and macrovascular complications significantly contribute to morbidity and mortality in patients with Diabetes Mellitus. Studies revealed that accurate glucose control over time prevents or delays microvascular complications in both type 1 and type 2 Diabetes Mellitus. Intensive treatment with insulin and/or oral antidiabetic drugs (OADs), however, significantly increases the risk of hypoglycemia which is the limiting factor in glycemic management of diabetes. Major depression has been shown to be a common morbidity in Diabetes Mellitus. Studies have shown that the risk of depression is twice as high among adults with chronic Diabetes Mellitus than

among the general population. In addition, among people with Diabetes Mellitus, those with more complications are most likely to be depressed. Depressive symptom severity in diabetic patients is a risk factor for poor glycaemic control.
Comorbid depression in Diabetes Mellitus is frequently treated with antidepressive agents which could further complicate glycaemic control. The mechanism behind antidepressant induced disturbances on glucose homeostasis has not been elucidated yet.

Study objective

The study objective is the assessment of influence on glucose homeostasis as a consequence of starting switching, discontinuing or doses changes with antidepressants in a population of diabetic patients.

Study design

Within a population of diabetic patients who are consulting the diabetes nurse in the hospital patients are screened who are starting, swithing or discontinuing a antidepressant or having a dose change with an antidepressant. For each intervention patient one control patient is selected. The outcome is defined as changes in insulin and/or oral antidiabetic use in the period of 182 days after intervention compared to the period of 30 days prior to intervention.

Study burden and risks

The extend of the burden and risks associated with participation consists of filling in a questionnaire. This will take 20 minutes of the patients time. Besides, an extra sample of blood will be collected from the patient for future DNA-research. This sample will be taken during a regular sample collection diabetes laboratory investigation .

Contacts

Public
Maaslandziekenhuis

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Scientific
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Postbus 5500
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diabetes Mellitus
Starting, discontinuing , switching or dose change with antidepressant

Exclusion criteria

<18 jaar

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-04-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2007
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL14904.096.06