

The prevalence of (symptomatic) hypoglycemia in well-controlled elderly patients with type 2 Diabetes Mellitus: the results of continuous glucose monitoring. An observational pilot study.

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

Summary

ID

NL-OMON42250

Source

ToetsingOnline

Brief title

Hypoglycemia and continuous glucose monitoring

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym

Diabetes

Research involving

Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: door het kenniscentrum zelf en daarnaast loopt er een subsidieaanvraag

Intervention

Keyword: Continuous Glucose Monitoring, Diabetes Mellitus, Elderly

Outcome measures

Primary outcome

Hypoglycemia < 3.0 mmol/L of at least 15 minutes.

Secondary outcome

- Hypoglycemia < 3.5 mmol/L of at least 15 minutes.
- Symptomatic hypoglycemia (<3.5 mmol/L of at least 15 minutes in combination with complaints of hypoglycemia).

Study description

Background summary

There is very limited data regarding hypoglycaemia rates in elderly patients. Randomised controlled trials often use age-specific inclusion criteria, or age-related exclusion criteria such as frequent comorbidities. And those elderly patients that are included in randomised trials are not representative for all elderly patients with diabetes treated in primary care. Therefore, data from observational studies are important, but again these data are lacking. The aim of the current pilot study is to investigate the prevalence of (symptomatic) hypoglycaemia in frail elderly patients with type 2 diabetes treated with sulphonylurea + metformin, and to gather data for a full-scale hypothesis-testing study. The aim of this large powered study will be to compare differences in the prevalence of hypoglycemic events between different SUs.

Study objective

The primary objective of this pilot study is to determine the prevalence of

(symptomatic) hypoglycaemia (<3.0 mmol/L of at least 15 minutes) in well-controlled (HbA1c <58 mmol/mol) frail elderly patients (>70 years) with type 2 diabetes treated with sulphonylurea and metformin, or metformin monotherapy.

Study design

A prospective observational cohort study.

Study burden and risks

Patients will have to perform SBGM (self blood glucose monitoring) and wear the CGM for five days. In addition, besides the small risk of local infection at site of needle insertion (for the CGMS), the risks from participating in this trial are minimal.

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

Patients are required to meet the following criteria:

- o known T2DM;
- o >70 years old;
- o HbA1c <58 mmol/mol;
- o Groningen Frailty Indicator score ≥ 4 ;
- o treatment with
 - * metformin only (any dosage); or
 - * metformin (any dosage) + gliclazide (any dosage); or
 - * metformin (any dosage) + glimepiride (any dosage).

Exclusion criteria

Patients with insufficient knowledge of the Dutch language to understand the requirements of the study, patients with advanced dementia, patients with known anemia, and patients with a terminal disease or an estimated life expectancy <3 months, will be excluded.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-12-2014

Enrollment: 25

Type: Actual

Ethics review

Approved WMO

Date: 24-11-2014

Application type: First submission

Review commission: METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21290

Source: NTR

Title:

In other registers

Register	ID
CCMO	NL51201.075.14
OMON	NL-OMON21290