Continuous glucose monitoring in well-controlled elderly patients with type 2 Diabetes Mellitus.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21290

Source
NTR

Brief title
-

Health condition

Older well-controlled patients with type 2 Diabetes Mellitus
Hypoglycaemia / hypoglycemie

Sponsors and support

Primary sponsor: Diabetes centre, Isala Clinics, Zwolle, the Netherlands
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Hypoglycaemia < 3.5 mmol/L of at least 15 minutes.
Symptomatic hypoglycaemia (<3.5 mmol/L of at least 15 minutes in combination with complaints of hypoglycaemia).

Study description

Background summary

The current national primary care guideline recommends gliclazide as the second pharmacological step in diabetes management. Unfortunately, there is very limited data regarding hypoglycaemia rates in elderly patients using SUs. As more than one quarter of the type 2 diabetes population in the Netherlands is older than 75 years, differences in the frequency of hypoglycaemic events between SUs could be relevant. These events can be easily reported by the CGMS. Previous studies with CGMS already showed us that (asymptomatic) hypoglycaemic events are easily missed in elderly patients. However, these studies did not use an appropriate control group. Data regarding the effects of SUs, and specifically gliclazide, are needed for confirming the safety of gliclazide in frail elderly patients treated in primary care.

Study objective

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 sulfonylurea and 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 the most commonly used sulfonylurea derivatives (SUs), glimepiride and gliclazide.

Study design

Visit 1: inclusion, informed consent, blood drawn for HbA1c measurement, Groningen Frailty index.
Visit 2 (day 1): baseline measurements, blood pressure measurements, CGMS implanted.
Day 1: CGMS implanted after breakfast, SMBG (4-5x);
Day 2: SMBG (N, VL, VA, VS);
Day 3: SMBG (N, VL, VA, VS);
Day 4: SMBG (N, VL, VA, VS);
Visit 3 (day 5): removal of CGMS, collection of patient diary.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

- known type 2 diabetes mellitus;
- >70 years old;
- HbA1c <58 mmol/mol;
- Groningen Frailty Indicator score ≥4;
- treatment with:
• metformin only (any dosage); or
• metformin (any dosage) + gliclazide (any dosage); or
• metformin (any dosage) + glimepiride (any dosage).

Exclusion criteria

- insufficient knowledge of the Dutch language to understand the requirements of the study;
- advanced dementia;
- known anemia;
- terminally ill or an estimated life expectancy <3 months.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-12-2014
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-01-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42250
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4829
NTR-old	NTR4952
CCMO	NL51201.075.14
OMON	NL-OMON42250

Study results

Summary results

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