

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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21290

Bron

NTR

Verkorte titel

-

Aandoening

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

Ondersteuning

Primaire sponsor: Diabetes centre, Isala Clinics, Zwolle, the Netherlands

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	11-12-2014
Aantal proefpersonen:	15
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	14-01-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42250
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4829
NTR-old	NTR4952

Register

CCMO

OMON

ID

NL51201.075.14

NL-OMON42250

Resultaten

Samenvatting resultaten

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