Metformin and sitagliptin in patients with impaired glucose tolerance and a recent TIA or minor ischemic stroke: A multicenter, randomized, open-label phase II trial.

Gepubliceerd: 15-12-2011 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25556

Bron
NTR

Verkorte titel
MAAS trial

Aandoening

Stroke, transient ischemic attack, impaired glucose tolerance.

Herseninfarct, TIA, gestoorde glucose tolerantie.

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Baseline adjusted difference in 2-hour post-load glucose levels at 6 months

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Impaired glucose tolerance (defined as a 2-hour post load glucose level 7.8-11.0 mmol/L) is present in one third of the patients with a TIA or ischemic stroke, and is associated with a two-fold risk of recurrent stroke. Intensive glucose control with oral antidiabetic drugs have been shown to reduce the rate of progression to diabetes type II in patients with impaired glucose tolerance. Our recent study suggests that the widely used oral glucose-lowering drug metformin is safe and improves glucose tolerance in patients with TIA or minor ischemic stroke and impaired glucose tolerance, but often leads to gastro-intestinal side effects resulting in permanent discontinuation. The novel antidiabetic drug sitagliptin seems equally effective with fewer side effects in patients with impaired glucose tolerance.

Objective:

We aim to compare the effectiveness, feasibility and safety of both metformin and sitagliptin in patients with TIA or minor ischemic stroke and impaired glucose tolerance. We will assess whether a slow increase in dose of metformin and better support and information on this treatment will reduce the incidence of side effects in these patients, and whether it will improve treatment compliance.

Study design:

Phase 2, multicenter, randomized, controlled, open-label trial with blinded outcome assessment.

Study population:

Patients 18 years or older with recent (<6 months) TIA or minor ischemic stroke (mRS≤3) and impaired glucose tolerance.

Intervention:

Patients will be randomized to receive either open-label metformin or sitagliptin or “no metformin” in a 1:1:2 ratio for 6 months. Patients allocated to metformin will start with 500 mg twice daily, which will be slowly increased in 6-weeks time to a daily dose of two times 1000 mg. Patients allocated to sitagliptin will be treated with a daily dose of 100 mg.

Main study parameters/endpoints:

Primary outcome measures were baseline adjusted differences of 2-hour post-load glucose; secondary outcome measures fasting glucose, glycosylated hemoglobin 1c (HbA1c) levels, tolerability and safety of metformin and sitagliptin at 6 months.

Doel van het onderzoek

We aim to compare the effectiveness, feasibility and safety of both metformin and sitagliptin in patients with TIA or minor ischemic stroke and impaired glucose tolerance. We will assess whether a slow increase in dose of metformin and better support and information on this treatment will reduce the incidence of side effects in these patients, and whether it will improve treatment compliance.

Onderzoeksopzet

At 2 weeks, 6 weeks and 3 months to record possible adverse events and to support continuation of treatment.
At 6 months to assess the primary and secondary outcome measures.

Onderzoeksproduct en/of interventie

Patients will be randomized to receive either open-label metformin or sitagliptin or “no metformin” in a 1:1:2 ratio for 6 months. Patients allocated to metformin will start with 500 mg twice daily, which will be slowly increased in 6-weeks time to a daily dose of two times 1000 mg. Patients allocated to sitagliptin will be treated with a daily dose of 100 mg.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. 18 years or older;

2. Clinical diagnosis of TIA, amaurosis fugax or minor ischemic stroke within the previous 6 months;

3. Impaired glucose tolerance (2-hour post-load glucose level 7.8-11.0mmol/L).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Diabetes mellitus;

2. History of diabetic ketoacidosis;

3. Symptoms of type 1 diabetes mellitus;

4. Signs of renal impairment (creatinin of 135 µmol/L or higher for men, and 110 µmol/L or higher for women);

5. Known liver disease or disturbed liver function tests (alanine amino transferase, aspartate amino transferase, alkaline phosphatase, or γ glutamyl transferase increased to more than twice the upper limit of typical values);

6. History of lactic acidosis;

7. Heart failure requiring pharmacological therapy;

8. Pancreatitis;

9. Chronic hypoxic lung disease;

10. Use of digoxin;

11. Pregnancy;

12. Breast feeding.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2014
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	15-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3048
NTR-old	NTR3196
Ander register	Erasmus Medical Center : MAAS
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A