LIMIT-1: Lowering the Incidence of vascular complications with Metformin in patients with Impaired glucose tolerance and a recent TIA or minor ischemic stroke: a phase 2, randomized, controlled trial

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Metformin will be tolerated in patients with TIA or minor ischemic stroke and will result in blood glucose lowering.

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

Samenvatting

ID

NL-OMON26223

Bron
NTR

Verkorte titel
LIMIT-1

Aandoening

glucose intolerance
metformin
TIA
stroke, ischemic
trial

Ondersteuning

Primaire sponsor: S.E. Vermeer, MD, PhD

Overige ondersteuning: No funding parties

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Tolerability of metformin treatment (measured as number of patients still on treatment after 3 months);
2. The safety of metformin treatment (which will be continuously monitored)
3. The adjusted difference in 2-hour post-load glucose levels at 3 months.

Toelichting onderzoek

Achtergrond van het onderzoek

Abstract
Background Impaired glucose tolerance, an intermediate metabolic state between normal glucose tolerance and diabetes mellitus defined by 2-hour post-load glucose levels of 7.8-11.0 mmol/L, is associated with an increased risk of stroke in patients with cardiovascular disease. Intensive glucose control with oral antidiabetic drugs have been shown to reduce the diabetes incidence in patients with impaired glucose tolerance without cardiovascular disease. Whether pharmacotherapeutical intervention reduce the risk of cardiovascular events in patients with TIA or minor ischemic stroke and impaired glucose tolerance is unknown.
Aim To examine the safety, tolerability, and effect on glucose metabolism of metformin treatment in non-diabetic patients with TIA or minor ischemic stroke and impaired glucose tolerance.
Design This is a phase 2, randomized, controlled, open-label trial with blind outcome assessment among 40 non-diabetic patients with impaired glucose tolerance who recently had a TIA or minor ischemic stroke. Patients will be randomized for metformin or no oral antidiabetic drug on top of optimal standard treatment including lifestyle advice. The primary outcomes will be the safety, and tolerability of metformin treatment and the adjusted difference in 2-hour post-load glucose levels at 3 months between treatment groups. Secondary outcomes will be the difference in fasting glucose levels, insulin resistance, body mass index, and percentage of patients with a normal glucose tolerance. All analyses will be done according to the intention-to-treat principle.

Doel van het onderzoek

Metformin will be tolerated in patients with TIA or minor ischemic stroke and will result in blood glucose lowering.

Onderzoeksproduct en/of interventie

Patients will be randomized for metformin or no oral antidiabetic drug (open-label) on top of optimal standard treatment, including lifestyle advice aimed at weight reduction and regular physical exercise. Patients allocated to metformin will be treated with metformin for 3 months from the day of randomization until study end. They will start with a daily dose of 500 mg that will be slowly increased in one-month time to a daily dose of 2,000 mg in two gifts. All patients will be followed for 3 months.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Men or women 18 years and over;
2. TIA/minor ischemic stroke (modified Rankin Score 3 or less) within 6 months;
3. Impaired fasting glucose (fasting glucose level of 5.6 to 6.9 mmol/L) and/or impaired

glucose tolerance (2-hour post-load glucose level of 7.8 to 11.0 mmol/L);
4. Informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Known or newly diagnosed diabetes mellitus;
2. Contraindication for metformin:
a. renal impairment (serum creatinine >135 micromol/L for men, and >110 micromol/L for women),
b. hepatic disease (liver enzymes increased twice the upper limit of normal), c. a past history of lactic acidosis,
d. cardiac failure requiring pharmacological therapy,
e. chronic hypoxic lung disease,
f. pregnancy,
g. breast feeding;
3. Severe comorbidity interfering with follow-up

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2007
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-03-2007
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	NL905
NTR-old	NTR929
Ander register	:
ISRCTN	ISRCTN54960762

Resultaten