Does treatment with rosiglitazone result in improved pancreatic beta-cell function as compared to glimepiride in metformin treated diabetes type 2 patients?

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By inducing a shift of fat out of the visceral compartment - among which the pancreas - into the subcutaneous compartment rosiglitazone results in improved pancreatic beta-cell function in type 2 diabetes patients, as compared to a...

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

Samenvatting

ID

NL-OMON27919

Bron
NTR

Verkorte titel
N/A

Aandoening

Type 2 diabetes.
Type 2 diabetes is a heterogeneous disorder involving varying levels of insulin insensitivity and impaired islet beta-cell function.

Ondersteuning

Primaire sponsor: Academic Medical Center - Amsterdam
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The peak insulin concentrations during the hyperglycaemic clamp protocol.

Toelichting onderzoek

Achtergrond van het onderzoek

Study title:

Does treatment with rosiglitazon result in improved pancreatic ß-cell function as compared to glimepiride in metformin treated diabetes type 2 patients?

Introduction:

Thiazolidinediones, a new class of insulin sensitizing agents, have been shown to induce a shift of fat out of the visceral compartment – among which the pancreas – into the subcutaneous compartment. This could also result in a restoration or preservation of endogenous insulin secretion capacity, loss of which is one of the fundamental defects in Type 2 diabetes. A recent study could not confirm this hypothesis, but various shortcomings in the design of this previous study can be noted, most notably a treatment period that is likely to have been too short, and the fact that patients were not using metformin, the standard treatment for type 2 diabetes.

Aim of the study:

To investigate the effect of rosiglitazon treatment on □-cell function in type 2 diabetes patients as compared to a sulfonylureumderivative, while both groups continue metformin treatment.

Design:

Twenty-two patients will be randomized to metformin with glimepiride 4 mg a day or metformin with rosiglitazon 8 mg a day.

Patients:

Eligible patients are those with Type 2 diabetes using metformin. Exclusion criteria are established coronary heart disease and previous use of a thiazolidinedione.

Measurements:

Patients will undergo a 200 min hyperglycaemic (aiming at 10 mmol/l) clamp with administration of glucagon-like peptide-1 (GLP-1) starting at 120 min (bolus injection of 4.5 pmol/kg followed by a continuous infusion of 1.5 pmol/kg/min until the end of the clamp) and an arginine (5 g) bolus at 180 min to elicit a further □-cell response. Twenty-six weeks later, the assessments will be repeated, again on metformin, other study medication taken until the morning before this assessment.

Outcome measures:

Primary outcome measure will be the peak insulin concentrations during the hyperglycaemic clamp protocol.

Burden for the participants:

The risk for participants is judged to be minor. Participation mainly requires an investment of time and undergoing insertion of the sensors and blood sampling.

8-Aug-2007: trial has stopped because of stop cause problems with inclusion of patients.

Doel van het onderzoek

By inducing a shift of fat out of the visceral compartment - among which the pancreas - into the subcutaneous compartment rosiglitazone results in improved pancreatic beta-cell function in type 2 diabetes patients, as compared to a sulfonylureumderivative, while both groups continue metformin treatment.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Patients will be randomized to 26 weeks of treatment with metformin with glimepiride 4 mg a day or metformin with rosiglitazone 8 mg a day.

Before the start of the treatment patients will undergo a 200 min. hyperglycaemic (aiming at 15 mmmol/l) clamp with administration of glucagon-like peptide-1 (GLP-1) starting at 120 min. and an arginine bolus at 180 min. to elicit a further beta-cell response.

Twenty-six weeks later, the assessments will be repeated, again on metformin, other study medication taken until the morning before this assessment.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Informed consent form signed;

2. Type 2 diabetes patients, accoring to WHO criteria;

3. Age 18-70 years;

4. Use of metformin, at least 500 mg a day;

5. HbA1c > 7.0% inclusive when on metformin alone, or > 6.5 % when on combination therapy of metformin and a sulfonylureumderivative.

Use of a sulfonylureumderivative is allowed, with a wash-out period of four weeks before the first assessments.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Established coronary heart disease;

2. Previous use of a thiazolidinedione.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-09-2004
Aantal proefpersonen:	22
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-02-2006
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	NL549
NTR-old	NTR605
Ander register	: N/A
ISRCTN	ISRCTN52245496

Resultaten

Samenvatting resultaten
N/A