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

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27919

Source
Nationaal Trial Register

Brief title
N/A

Health condition

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

Sponsors and support

Primary sponsor: Academic Medical Center - Amsterdam
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

The peak insulin concentrations during the hyperglycaemic clamp protocol.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

N/A

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Established coronary heart disease;

2. Previous use of a thiazolidinedione.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-09-2004
Enrollment:	22
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-02-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL549
NTR-old	NTR605
Other	: N/A
ISRCTN	ISRCTN52245496

Study results

Summary results
N/A