

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

1 - Does treatment with rosiglitazone result in improved pancreatic beta-cell functi ... 21-06-2025

The peak insulin concentrations during the hyperglycaemic clamp protocol.

Secondary outcome

N/A

Study description

Background summary

Study title:

Does treatment with rosiglitazone result in improved pancreatic β -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 rosiglitazone treatment on β -cell function in type 2 diabetes patients as compared to a sulfonylurea derivative, while both groups continue metformin treatment.

Design:

Twenty-two patients will be randomized to metformin with glimepiride 4 mg a day or metformin with rosiglitazone 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 β -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 sulfonylurea derivative, 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 mmol/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

Public

Academic Medical Center, Department of Internal Medicine F4-257,
P.O. box 22660
S.G.H.A. Swinnen
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667836

Scientific

Academic Medical Center, Department of Internal Medicine F4-257,
P.O. box 22660
S.G.H.A. Swinnen
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5667836

Eligibility criteria

Inclusion criteria

1. Informed consent form signed;
2. Type 2 diabetes patients, according 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