Pioglitazone Influence of triglyceride Accumulation in the Myocardium in Diabetes.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21475

Source
NTR

Brief title
The PIRAMID study

Health condition

Type 2 Diabetes Mellitus, Heart Disease

Sponsors and support

Primary sponsor: VU medical center
De Boelelaan 1117
1081 HV Amsterdam
The Netherlands
Source(s) of monetary or material Support: Grant by Eli Lilly Nl

Intervention

Outcome measures

Primary outcome

Changes in cardiac function and metabolism following treatment with PPARg agonist versus current state of the art therapy, metformin.

Secondary outcome

Glucose and FFA uptake by adipose tissue and skeletal muscle Cardiac high-energy-phosphate (HEP) metabolism.
Hemodynamic and vascular parametersBody composition (body mass index (BMI), waist, adipose tissue distribution, including liver fat content, body fat percentage and fluid retention) Plasma parameters of glycemic control and lipoprotein metabolism Circulating levels of markers of inflammation, coagulation activation, fibrinolysis and endothelial functions Whole-body insulin sensitivity (by clamp).

Study description

Background summary

Background/hypothesis:

Patients with type 2 diabetes mellitus (DM2) have a considerably higher risk to develop cardiac disease with a poorer outcome. Ectopic triglyceride (TG) accumulation underlies diabetic cardiomyopathy. These cardiac abnormalities can be reversed by lowering myocardial TG using a peroxisome proliferator-activated receptor (PPAR) g agonist. Metformin, the present gold standard treatment for type 2 diabetes, might also have cardioprotective properties due to its recently proposed mechanism of action.

Study objective

Lipotoxicity-related cardiac abnormalities can be reversed by PPAR g agonist therapy in type 2 diabetes patients.

Study design

N/A

Intervention

80 subjects on monotherapy sulfanylurea for at least 10 weeks will be enrolled. Following, participants will be randomised to Metformin or Pioglitazone for 24 weeks.
Group 1: Metformin;
Group 2: Pioglitazone
10 healthy subject will only undergo baseline measurements.

Contacts

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Eligibility criteria

Inclusion criteria

Type 2 Diabetes PatientsMales, 45-65 years, DM2 (diagnosed according to WHO criteria, treated by monotherapy of sulfanylurea (i.e. unchanged during >30 days prior to inclusion). At least three month stable HbA1c (<8.5%) under this therapy.
Sitting blood pressure <150/85 mmHg with or without antihypertensive drugs, BMI<32 kg/m2.Healthy volunteers, Healthy male subjects, 45-65 years, Normal sitting blood pressure <150/85 mmHg, BMI<32 kg/m2. Normal glucose tolerance as assessed by 75-g oral glucose tolerance test.

Exclusion criteria

Type 2 Diabetes Patients, CAD, Active malignant disease, Impaired renal function (serum creatinine > 176 mmol/L), Weight >/= 45 kg (because of 11C-palmitate tracer), Anti-coagulant therapy, Severe
obstructive lung disease; hereditary lipoprotein disease, Impaired hepatic function (defined as ALT > 3 ULN) or a history of liver disease, Inability to understand study information, inability / unwillingness to sign informed consent, Substance abuse, Familial polyposis coli,

<3 months after participation in other clinical trials.
Other research projects, whereby radiation is used. Hemoglobin <8 mmol/l, Metal implants and claustrophobia, incompatible with CMR.
Congestive heart failure (NYHA functional score > I), atrial fibrillation or history of sustained ventricular tachycardia.
Stroke within 6 months prior to enrollment.
Microvascular complications, including:
diabetic nephropathy, proliferative retinopathy, symptomatic macrovascular complications and/or (autonomic) neuropathy, except for background diabetic retinopathy.
Leg ulcers, gangrene. Hyper sensibility to study medication.
Current use of TZD/fibrates Healthy volunteersHistory or current cardiovascular diseaseDyslipidemia, requiring pharmacological treatment according to the Dutch Cholesterol Consensus 1998

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2004
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	05-09-2005
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	NL145
NTR-old	NTR180
Other	: N/A
ISRCTN	ISRCTN53177482

Study results

Summary results
N/A