# Pioglitazone Influence of triglyceride Accumulation in the Myocardium in Diabetes.

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

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

## Samenvatting

### ID

NL-OMON21475

**Bron**
NTR

**Verkorte titel**
The PIRAMID study

**Aandoening**

Type 2 Diabetes Mellitus, Heart Disease

### Ondersteuning

**Primaire sponsor:** VU medical center
De Boelelaan 1117
1081 HV Amsterdam
The Netherlands
**Overige ondersteuning:** Grant by Eli Lilly Nl

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

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.

# Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Dubbelblind |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 01-09-2004 |
| Aantal proefpersonen: | 90 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

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|---|---|
| Datum: | 05-09-2005 |

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 | NL145 |
| NTR-old | NTR180 |
| Ander register | : N/A |
| ISRCTN | ISRCTN53177482 |

# Resultaten

**Samenvatting resultaten**
N/A