

# The role of free fatty acids in the glucose-lowering effects of thiazolidinediones

**Submission date**

14/02/2006

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

14/02/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

24/08/2009

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Study objectives

Thiazolidinediones (TZDs, Pioglitazone) lower free fatty acids (FFA) in plasma via increased insulin sensitivity (= decreased lipolysis) in adipose tissue. The decrease in plasma FFA results in increased insulin sensitivity in skeletal muscle. Increasing plasma FFA to baseline levels while on TZD treatment will decrease peripheral insulin sensitivity to pre-treatment levels indicating that the mechanism of action of Pioglitazone is not directly on muscle but via lowering of plasma FFA due to the beneficial effects on adipose tissue.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Received from local medical ethics committee

## Study design

Randomised single blind placebo controlled parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Diabetes Mellitus type II (DM type II)

## Interventions

Treatment with pioglitazone 30 mg once a day or placebo.

Infusion of a lipid emulsion on the third study day in the active treatment group.

## Intervention Type

Drug

## Phase

Not Specified

## Drug/device/biological/vaccine name(s)

Pioglitazone

**Primary outcome measure**

1. Basal glucose production and plasma FFA
2. Peripheral insulin sensitivity
3. Insulin-mediated suppression of FFA (= insulin sensitivity of adipose tissue)

**Secondary outcome measures**

Changes in concentrations of ceramide and glycosphingolipids in skeletal muscle.

**Overall study start date**

01/09/2002

**Completion date**

31/05/2005

## **Eligibility**

**Key inclusion criteria**

1. Obese patients with Diabetes Mellitus type II (DM II)
2. Body mass index (BMI) >25 kg/m<sup>2</sup>
3. Treatment for DM II with oral medication only
4. Moderately regulated DM II

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

13

**Key exclusion criteria**

1. Use of insulin
2. Use of fibrates
3. Plasma creatinine >150 µmol/l
4. Transaminases >2 x upper limit of reference value
5. Impaired cardiac function or angina pectoris
6. Familial lipid metabolism disorder
7. Premenopausal women
8. Epilepsy
9. Proliferative retinopathy

**Date of first enrolment**

01/09/2002

**Date of final enrolment**

31/05/2005

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre****Academic Medical Center**

Amsterdam

Netherlands

1100 DD

## **Sponsor information**

**Organisation**

Academic Medical Centre (Netherlands)

**Sponsor details**

Department of Endocrinology and Metabolism

P.O. Box 22660

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03t4gr691>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Fellowship award from the European Society of Parenteral and Enteral Nutrition

**Funder Name**

Eli Lilly BV (Netherlands)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/01/2007		Yes	No