

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

Submission date 14/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/08/2009	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M.J.M. Serlie

Contact details
Academic Medical Center
Department of Department of Endocrinology and Metabolism (F5-169)
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
m.j.serlie@amc.uva.nl

Additional identifiers

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Changes in concentrations of ceramide and glycosphingolipids in skeletal muscle.

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/m²
3. Treatment for DM II with oral medication only
4. Moderately regulated DM II

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Use of insulin
2. Use of fibrates
3. Plasma creatinine >150 umol/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)

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

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?
Results article	results	01/01/2007		Yes	No