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

Submission date	Recruitment status	[_] Prospectively registered
14/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/08/2009	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/m2
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 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)

Sponsor details
Department of Endocrinology and Metabolism
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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?
Results article	results	01/01/2007		Yes	No