

Fatty Acid Induced Oxidative Stress: its role in preventing hypoglycemia

Submission date 09/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/09/2009	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
NTR517

Study information

Scientific Title

Acronym

FIOS: Fatty acid Induced Oxidative Stress

Study objectives

Elevated levels of Free Fatty Acids during fasting induce oxidative stress and cause insulin resistance to maintain euglycemia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Non-randomised open label placebo controlled crossover group trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Other

Participant information sheet

Health condition(s) or problem(s) studied

No condition, healthy person

Interventions

Subjects will undergo a period of fasting and are assigned to receive either acipimox (inhibitor lipolysis) 250 mg 4dd or placebo. Hereafter insulin sensitivity will be measured using stable isotope technique. Furthermore regulating hormones and lipids will be measured. Muscle specimens (v. lateralis) will be obtained for determination of intramyocellular lipids and transcription factors.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

acipimox

Primary outcome measure

Insulin resistance, Free fatty acids and oxidative stress with and without acipimox.

Secondary outcome measures

Other measures of glucosehomeostasis: glucoregulatory hormones, (adipo)cytokines.

Overall study start date

01/01/2006

Completion date

01/03/2006

Eligibility

Key inclusion criteria

1. 6 healthy men
2. 18-38 years
3. Body mass index (BMI) 20-25
4. Stable weight during the last 3 months

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

38 Years

Sex

Male

Target number of participants

6

Key exclusion criteria

1. Diabetes
2. Diabetes first degree relatives
3. Hypercholesterolemia
4. High intensity sport activities
5. Positive oral glucose tolerance testing

Date of first enrolment

01/01/2006

Date of final enrolment

01/03/2006

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Center

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (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

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands), Department of Endocrinology and Metabolism

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