# Fatty Acid Induced Oxidative Stress: its role in preventing hypoglycemia

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

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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#### Contact details

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# Additional identifiers

Protocol serial number 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

## Study type(s)

Other

## 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 lipilysis) 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(s)

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

## Key secondary outcome(s))

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

# 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** 

## Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

# Upper age limit

38 years

#### Sex

Male

#### 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)

#### **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**

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration