ISRCTN85121743 https://doi.org/10.1186/ISRCTN85121743

Fatty Acid Induced Oxidative Stress: its role in preventing hypoglycemia

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr M.R. Soeters

Contact details
Academic Medical Center
Dept of Endocrinology & Metabolism
F5-162
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 7672/9111
M.R.Soeters@amc.uva.nl

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 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 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
Amsterdam
Netherlands
1100 DD

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