

# Effects of acute elevation of plasma free fatty acids on cardiac lipid accumulation in healthy lean young men

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The major research objective is:- to examine whether elevation of plasma FFAs results in cardiac lipid accumulation and whether this influences cardiac function negatively. Additional research objective: - to examine whether cardiac lipid content is...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32915

### Source

ToetsingOnline

### Brief title

Free fatty acids and cardiac lipids

### Condition

- Heart failures
- Diabetic complications

### Synonym

cardiac steatosis, heart failure

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** cardiac lipid content, diastolic function, plasma free fatty acids, systolic function

## Outcome measures

### Primary outcome

Cardiac lipid content after the high FFA condition compared to the low FFA condition and the cardiac function and energy status associated with it.

### Secondary outcome

Cardiac lipid content before exercise compared to after exercise.

## Study description

### Background summary

There is increasing evidence that Cardiac lipid content (IntraCardiomyoCellular Lipid, ICCL), is involved in the etiology of dilated cardiomyopathy and heart failure<sup>4,5</sup>. We hypothesize that the heart is passively taking up FFAs when the availability is high, thereby leading to an increased storage. To test this hypothesis, we want to manipulate FFA levels and monitor cardiac lipid content and cardiac function and energy status.

Recently, proton magnetic resonance spectroscopy has been adapted to enable quantification of lipid content in cardiac muscle<sup>16,17</sup>.

### Study objective

The major research objective is:

- to examine whether elevation of plasma FFAs results in cardiac lipid accumulation and whether this influences cardiac function negatively.

Additional research objective:

- to examine whether cardiac lipid content is decreased after cycling (as it is the case in skeletal muscle).

### Study design

Cardiac lipid content and cardiac function will be determined in a condition with high plasma FFA (cycling and recovery in fasted state) and in a low FFA condition (cycling and recovery with glucose supplementation). Remaining fasted during cycling and recovery has been shown to result in strongly increased FFA

levels, while glucose supplementation completely blunts the increase in FFA.

## **Intervention**

Subjects will perform a two-hour cycling test, once fasted (high FFA condition) and once with glucose supplementation (low FFA condition). Before and after the cycling test and again after a three-hour recovery period, cardiac lipid, cardiac function and energy status will be performed by MRI/MRS.

## **Study burden and risks**

First visit: determination of maximal aerobic capacity and body composition (ca 1.5 hours). Second and third visit (test days, ca. 8h): After a baseline MRI/MRS-scan, subjects will cycle for two hours, immediately after cycling another MRI/MRS-scan will be performed and after two more hours of recovery another MRI/MRS-scan will be performed. During cycling and recovery period, indirect calorimetry will be performed and blood will be sampled repeatedly (10 ml) from a catheter placed in the antecubital vein. On one visit, subjects will get a glucose drink, on the other occasion only water. The experimental procedures are without risks, except for insertion of a catheter for blood sampling, which can occasionally cause a local haematoma or bruise to occur. MRS is a safe procedure (no ionizing radiation), with no known health risk as long as none of the exclusion criteria is met.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

age (18-35)

BMI (18-25)

sex (male)

### Exclusion criteria

Contraindications for MRI (e.g. electronic implants such as pace-makers or neurostimulators, iron particles in eyes and claustrophobia)

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2008
Enrollment:	20

Type:

Actual

## Ethics review

Approved WMO

Date: 19-11-2008

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

**Register**

CCMO

**ID**

NL24637.068.08