

Adipose tissue in overweight individuals with and without the metabolic syndrome; differences in free fatty acid profile in Fasting and Fed state using 1H-MR-spectroscopy.

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1. Evaluation of differences in free fatty acid (FFA) profiles of several adipose tissue depots, expressed as FFA ratios, between metabolically healthy obese subjects and metabolically unhealthy obese subjects (e.g. subjects with metabolic syndrome...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON39951

Source

ToetsingOnline

Brief title

AFFECT 2

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym

adipose tissue dysfunction, overweight

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: Adipose tissue, Free fatty acids, Magnetic Resonance, Spectroscopy

Outcome measures

Primary outcome

1. Free fatty acid ratios

Triglycerides (TG), poly unsaturated fatty acids (PUFA) and total unsaturated fatty acids (TUFA) will be measured with spectroscopy.

The PUFA/TG, TUFA/TG and the PUFA/TUFA ratio will be calculated after standardization of the measurements with respect to voxelsize and watercontent.

2. Serum triglycerides vs adipose tissue triglycerides

The change in concentration of triglycerides in serum (peripheral blood) will be compared to the change in concentration of triglycerides in the adipose tissue measured with spectroscopy, both before and after an oral fat load.

Secondary outcome

Not applicable

Study description

Background summary

Adipose tissue dysfunction can be diagnosed with ^1H -MR-spectroscopy, quantifying free fatty acids. Moreover, differences can be encountered in the free fatty acid distribution between lean and obese persons and between persons

with and without characteristics of the metabolic syndrome. The development of adipose tissue dysfunction is partly driven by the amount of adipose tissue present in the body. To what extent diet, exercise and other environmental factors play a role in the development, maintenance and amelioration of adipose tissue dysfunction is topic of current research

Study objective

1. Evaluation of differences in free fatty acid (FFA) profiles of several adipose tissue depots, expressed as FFA ratios, between metabolically healthy obese subjects and metabolically unhealthy obese subjects (e.g. subjects with metabolic syndrome) using 1 (H)-MR-spectroscopy. (MRS)
2. Evaluation of differences in FFA profiles of several adipose tissue depots (expressed as FFA ratios) before and after an oral fat load in metabolically healthy obese subjects and metabolically unhealthy obese subjects (e.g. subjects with metabolic syndrome) using 1 (H)-MR-spectroscopy.

Study design

A cross-sectional study with 2 MRS measurements per individual, one fasting and 1 after ingestion of an oral fat load.

Study burden and risks

Participants are asked to refrain from high fat foods for 3 days before MRS measurements take place, and to ingest an oral fat load on the day of the MRS measurements. Per participant there will be 2 MRS measurements and 3 bloodsamples will be drawn. No contrast will be given during the MRS. Therefore, we consider this study to be low-risk.

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

1. Between ages of 18 and 70 years.
2. Male or female
- 3.a. Metabolic syndrome group: BMI ≥ 25 kg/m² and presence of the metabolic syndrome.
- 3.b. No metabolic syndrome group: BMI ≥ 25 kg/m² and absence of the metabolic syndrome.

Exclusion criteria

1. Known cardiovascular disease
2. Known renal, liver or pulmonary disease
3. Diabetes mellitus
4. Use of medication (except for oral contraceptives, proton pump inhibitor*s, inhalation medication or topical unguents)
5. Pregnancy or lactation
6. Claustrophobia
7. Waist circumference too large to fit MRI (>200 cm)
8. Metallic devices in the body of the participant

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO	
Date:	30-10-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	24-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	ID
CCMO	NL41412.041.12