Imaging abdominal fatmass and its components with spectroscopy

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1. To evaluate and optimalize a 3 Tesla MR protocol for the determination of the lipid composition of abdominal adipose tissue; by means of spectroscopy. 2.Determination of the reproducibility of MR-spectroscopy of abdominal adipose tissue. Both...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36650

Source
ToetsingOnline

Brief title
AFFECT

Condition

- Other condition

Synonym
dysfunctional abdominal fat, dysfunctional visceral adipose tissue

Health condition

dysfunctie van abdominaal vetweefsel

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: abdominal, adipose tissue, imaging, spectroscopy

Outcome measures

Primary outcome

1. Unit defining the outcome of the MR-spectroscopic measurements. Again, because MR-spectroscopy has not been performed on abdominal adipose tissue before, no predefined unit is available.

With the spectroscopy measurements of abdominal adipose tissue, we want to be able to distinguish different lipid components at their known place in the spectrum. These peaks should include:

- the water peak at 4.65 ppm

- the triglyceride peak at 0.9 and 1.3 ppm

- the total unsaturated fatty acids peak at 5.4 ppm

- the poly unsaturated fatty acids peak at 2.8 ppm

These peaks should be easily determinable and should not overlap each other , making calculation of AUC*s possible. If these conditions are met, data will be regarded as adequate. If other peaks are present in the spectra of the abdominal adipose tissue, these will be analyzed in the same manner. With calculated AUC*s of each of these components ratio*s of the lipid components

relative to water can be calculated.

These ratio*s in abdominal adipose tissue can be compared to the same ratio*s obtained from spectroscopic measurements in other tissues, for example subcutaneous adipose tissue or hepatic tissue. When related to other tissue*s a comparison can be made regarding the amount of the different lipidcomponents. For this study, because we do not know what will be the most appropriate tissue to compare the spectroscopic measurements of abdominal adipose tissue to, we want to perform spectroscopy of liver, subcutaneous adipose tissue, skeletal muscle and spleen.

Because we want to determine whether the ratio's differ when a person has a small or large amount of abdominal adipose tissue, half of the participantis will have a waistcircumference of >88cm (women) or >102cm (men).

2. Reproducibility of spectroscopic measurements
Both interscan (i.e. intra-individual) and interobserver reproducibility will be defined using Bland-Altman plots and interclass correlation coefficients.

Secondary outcome

1. To compare spectroscopic measurements of participants with and without (laboratory) measurements of metabolic syndrome.

2. To compare adipokine profiles of participants with spectroscopic

measurements (only when technique seems feasible).

Study description

Background summary

Dysfunctionality of adipose tissue is currently determined by measuring plasma levels of adipokines/cytokines obtained in peripheral blood or by sampling adipose tissue during abdominal surgery. Both methods have considerable disadvantages; peripheral bloodsamples might not be representative for the actual metabolic activity of abdominal adipose tissue and adipose tissue biopsies can only be performed when patients undergo surgery for other reasons. To be informed about the (dys) functionality of abdominal adipose tissue may help to understand pathophysiology, may direct therapy against obesity, diabetes and cardiovascular diseases and may provide tools for predicting the risk of diabetes and vascular diseases. MR-spectroscopy of the abdomen might be a non-invase and reproducible way to obtain information on the metabolic activity of abdominal adipose tissue.

Study objective

1. To evaluate and optimalize a 3 Tesla MR protocol for the determination of the lipid composition of abdominal adipose tissue; by means of spectroscopy.

2.Determination of the reproducibility of MR-spectroscopy of abdominal adipose tissue. Both interscan (i.e. intra-individual; comparing the two MR scans of each participant) and interobserver reproducibility will be determined.

Study design

A cross-sectional study with 2 separate MR-spectroscopy measurements per individual for purposes of scanoptimalization and reproducibility.

Study burden and risks

Participants will be asked to visit the hospital twice, during the first visit a MR-spectroscopy will take place and anthropometric measurements will be taken. Besides those measurements, 13 ml of blood will be drawn during the first visit; 1 tube will be used for direct measurement of glucose, insulin and lipidprofile. The rest of the blood will be stored to be able to determine a adipokineprofile when the technique of spectroscopy seems feasible.
During the second visit, the MR-spectroscopy will be repeated, no other tests will take place. Participants will be asked to fast overnight before the MRI scans take place.

Making these MRI scans and performing the other measurements gives a very small, almost negligible burden for the participant. As far as we know, all of the procedures used in this study have no short- or longterm side-effects.

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 65 years.
2. Healthy volunteers
3. Male or female

Exclusion criteria

1. Known cardiovascular disease
2. Known renal, liver or pulmonary disease
3. Use of medication (except for oral anticonceptives, PPI*s, inhalation medication or topical unguents)
4. Pregnancy or lactation
5. Severe claustrophobia
6. Waist circumference too large to fit MRI. (> 200cm)
7. Metallic devices in the body

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-05-2011
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	MRI scan 3 tesla
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	08-03-2011
Application type:	First submission

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	NL34282.041.10