Association between Brown Adipose Tissue and metabolic health in patients with manifest vascular disease or at high risk for cardiovascular events.

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1. To evaluate and optimize a protocol for quantifying brown adipose tissue with MRI and to assess BAT volume per patient. 2. To assess the reproducibility of MRI measurments by determining, inter-scan, intra-observer and inter-observer variability…

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

Summary

ID

NL-OMON41498

Source
ToetsingOnline

Brief title
Imaging brown adipose tissue with MRI.

Condition

- Other condition

Synonym
brown adipose tissue

Health condition

Vetweefsel

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Niet van toepassing

Intervention

Keyword: Brown Adipose Tissue (BAT), Cardiovascular disease (CVD), Magnetic Resonance Imaging (MRI)

Outcome measures

Primary outcome

Reproducibility of measuring BAT volume (mL) within the supraclavicular fossae

by determining inter-scan, inter-observer and intra-observer variability.

Addendum.

Adipose tissue estimated Fat Fraction. From this a volume estimation of brown

adipose tissue can be derived.

Secondary outcome

Not applicable.

Study description

Background summary

Brown Adipose Tissue (BAT) is responsible for non-shivering thermogenesis using triglycerides and glucose as its substrate. Because BAT might be an attractive target in diminishing or preventing obesity and obesity related cardiovascular disease, reliable and reproducible quantification of BAT in patients at risk for or having these diseases is highly desirable. MRI could address the need for quantification of BAT. However, although few studies already have used this new MRI technique in young adults without cardiovascular disease, it has never been performed in older patients with cardiovascular disease and studies

regarding feasibility and reproducibility within this population are lacking.

Addendum.
Aforementioned MRI technique is currently feasible and displays high reproducibility.

Study objective

1. To evaluate and optimize a protocol for quantifying brown adipose tissue with MRI and to assess BAT volume per patient.
2. To assess the reproducibility of MRI measurments by determining, inter-scan, intra-observer and inter-observer variability in BAT volume.

Addendum.
3. To quantify the relation between Fat Fraction measurements of supraclavicular and subcutaneous adipose tissue depots and patient characteristics (BMI and metabolic dysfunction) in an adult population of patients with manifest vascular disease or at high risk for cardiovascular events.

Study design

The design of this study is observational and cross-sectional.

At the scheduled appointment participants will come to the hospital to undergo a MRI scan wich is expected to take around 1 hour in total.

BAT volume (mL) is estimated from differences in MRI Fat signal Fractions (FF) values and differences in MRI T2*values between the bilateral supraclavicular fossae (presumably BAT) and adjacent subcutaneous tissues (presumably WAT).

Study burden and risks

The SMART cohort comprises patients with cardiovascular disease. The effort asked (MRI measurement of 1 hour) of participants is regarded as acceptable and in proportion to the incentives. Patients do not have to be in a fasting state. MRI does not involve ionizing radiation and no major risks are known with regard to making a MRI. By participating in this MRI study SMART patients will not experience direct benefits themselves, but with participation they will contribute to scientific research in imaging of brown adipose tissue, which, in the future might prove to be a valuable therapeutic target in obesity and obesity related cardiovascular disease.

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

Patients participating in the SMART cohort (protocol number 96-048).

Exclusion criteria

- Pregnancy or lactation.
- Mentally incapacitated subjects.
- Claustrophobia.
- Waist circumference >200cm.
- Metallic devices in the body of the participant such as cardioverter-defibrillators (AICD/ICD), pacemakers, cochlear implants, implanted insulin pumps, endoscopic (gastric) or aneurysm (brain) clips according to the UMCU MRI guidelines.

(https://richtlijn.mijnumc.nl/Beeld/MRI/Documents/MRI%20Veiligheid%20MRI%20contra-indicaties.pdf)
- Patients with HIV infection.

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):	16-04-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	20-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	12-03-2015
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	NL46994.041.13