Activation of Brown Adipose Tissue in Old and Young Individuals

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Primairy objective: To investigate whether the sympathetic stimulation of BAT, as assessed

with a MIBG SPECT-CT scan, differs between young and elderly subjects. Secondary

Objectives: 1) To investigate whether the slope of the correlation between...

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Glucose metabolism disorders (incl diabetes mellitus)

Study type Observational invasive

Summary

ID

NL-OMON39994

Source

ToetsingOnline

Brief title

Activation of Brown Adipose Tissue and Age

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Age related factors

Synonym

Obesity, Overweight and age

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Eigen stichting

Intervention

Keyword: Age, Brown Adipose Tissue, Sympathetic activation

Outcome measures

Primary outcome

Difference in semi quantitative uptake value of the tracer MIBG visualised with

SPECT-CT in BAT (younger versus older individuals).

Secondary outcome

The correlation between semi-quantitative uptake of MIBG and SUV of FDG in

young and older individuals will be calculated with a Pearson correlation

coefficient.

P-values for the difference in resting energy expenditure during thermoneutral

conditions and during mild cold-exposure will be calculated with independent

sample t-tests. Subsequently, the correlation between this difference in

resting energy expenditure and the sympathetic stimulation of BAT as assessed

with MIBG (and with metabolic BAT activity as assessed with FDG), will be

calculated with a Pearson correlation coefficient.

The correlation between insulin resistance in different age groups, and

semi-quantitative uptake of MIBG, or SUV of FDG will be calculated with a

Pearson correlation coefficient

In view of the limited size of the study, no multivariate analyses will be

performed.

Study description

Background summary

Brown adipose tissue (BAT) is known for its capacity to burn excess energy as part of a process called non-shivering thermogenesis. Several studies have shown that BAT activity is lower with increasing age, the exact explanation for this is not known. Since BAT is principally activated by stimulation via the sympathetic nervous system, the diminishing BAT activity with increasing age may be a result of relatively low sympathetic stimulation of BAT. In a previous study (METC 10/307, NL34861.018.10), we were able to quantitatively measure and visualize the sympathetic stimulation of BAT using I-123 Metaiodobenzylguanidine (MIBG) SPECT-CT scans. In this study we aim to determine whether the sympathetic stimulation of BAT changes with increasing age in individuals and if so, how this relates to the metabolic activity of BAT.

This research will provide insight into the mechanism of brown fat, which may help us to develop methods to combat obesity and diabetes.

Study objective

Primairy objective: To investigate whether the sympathetic stimulation of BAT, as assessed with a MIBG SPECT-CT scan, differs between young and elderly subjects.

Secondary Objectives:

- 1) To investigate whether the slope of the correlation between sympathetic stimulation of BAT as assessed with a MIBG SPECT-CT scan, and BAT activity itself as assessed with 18-F fluorodeoxyglucose (FDG) PET-CT, differs between young and elderly subjects.
- 2) To determine whether there is a difference in energy expenditure during thermoneutral conditions and during mild cold exposure (in young and elderly subjects).
- 3) To determine whether the difference in resting energy expenditure during thermoneutral conditions and during mild cold exposure correlates with the sympathetic stimulation of BAT as assessed with MIBG, and with metabolic BAT activity as assessed with FDG (in young and elderly subjects).
- 4) To determine whether the difference insulin sensitivity correlates with the sympathetic stimulation of BAT as assessed with a MIBG SPECT-CT scan, and with metabolic BAT activity as assessed with FDG PET-CT (in young and elderly subjects).

Study design

Observational design with invasive measurements

Study burden and risks

Included subjects will visit the AMC hospital on 3 occasions.

3 - Activation of Brown Adipose Tissue in Old and Young Individuals 14-05-2025

Visit 1: Informed consent, medical history, vital signs, laboratory measurements, oral glucose tolerance test, electrocardiogram (ECG). Total blood drawn: 67.5 ml.

Visit 2: Cold exposure, Intravenous administration of FDG, measurement of resting energy expenditure, core body temperature, and an EMG, during cold and FDG PET-CT scan.

Visit 3: Cold exposure, Intravenous administration of MIBG Visit 4 (24 hours after visit 3): MIBG SPECT-CT scan (no new infusion of MIBG) and measure of resting energy expenditure at thermoneutrality.

The resulting dose from the radioactive tracers + the scans is 9.6 mSv. The placement of an intravenous canula can be an unpleasant experience and there is a small chance of developing flebitis at the site of the intravenous canula. The placement of the rectal thermometer can be an unpleasant experience.

There is no direct benefit for the volunteers. This research will provide insight into the mechanism of brown fat activation, which may help us to develop methods to combat obesity and diabetes.

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

Male Caucasian Origin 18-65 years old BMI range 19-27kg/m2

Subjects should be able and willing to give informed consent

Exclusion criteria

Renal failure (creatinine >135 mmol/L)

Daily use of prescription medicine

Prior participation in a research protocol involving radiation exposure in the last 2 years

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Control: Active

Primary purpose: Basic science

Recruitment

NI

Recruitment status: Recruitment stopped

Start date (anticipated): 09-04-2013

Enrollment: 24

Type:	Actual

Ethics review

Approved WMO

Date: 21-02-2013

Application type: First submission

Review commission: METC Amsterdam UMC

Approved WMO

Date: 28-05-2013

Application type: Amendment

Review commission: METC Amsterdam UMC

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 NL42422.018.12