Activation of brown adipose tissue in lean and obese men

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Main objectiveTo investigate whether the sympathetic stimulation of BAT, as assessed with a MIBG SPECT-CT scan, differs between lean and obese individuals.Secondary Objectives: To investigate whether the slope of the correlation between sympathetic...

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

Summary

ID

NL-OMON39965

Source
ToetsingOnline

Brief title
Activation of brown adipose tissue and weight status

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
morbidly overweight, Obesity

Health condition

overgewicht

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: eigen stichting

Intervention

Keyword: Brown adipose tissue, Sympathetic activation, Weight status

Outcome measures

Primary outcome

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

SPECT-CT in BAT (lean vs obese individuals)

Secondary outcome

Difference in correlation between semi-quantitative uptake of MIBG and standard

uptake value of FDG (lean vs obese individuals)

Correlation between the difference in resting energy expenditure during

thermoneutral conditions and during mild cold exposure and semi-quantitative

uptake of MIBG, or standard uptake value of FDG

Study description

Background summary

Brown adipose tissue (BAT) has recently been identified as a possible mean to significantly influence energy expenditure and glucose metabolism. Several studies have shown that brown adipose tissue activity is much lower in obese individuals when compared to their lean peers. The exact explanation for this is not understood. As stimulation by the sympathetic nervous system is a principal driving force for BAT activation in humans, the relatively low BAT activity in obese individuals may be the result of a relatively low sympathetic stimulation of BAT. In a previous study, we were able to quantitatively measure and visualize the sympathetic stimulation of BAT using MIBG SPECT-CT scans. In

this study we aim to determine whether the sympathetic stimulation of BAT differs between lean and obese individuals and if so, how this affects the metabolic activity of BAT. Furthermore, we want to investigate the relation between the sympathetic stimulation and metabolic activity of BAT with energy expenditure in these individuals.

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

Main objective
To investigate whether the sympathetic stimulation of BAT, as assessed with a MIBG SPECT-CT scan, differs between lean and obese individuals.

Secondary Objectives:

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 FDG PET-CT, differs between lean and obese individuals.

To determine whether the difference in resting energy expenditure during thermoneutral conditions and during mild cold exposure (i.e when BAT is active) correlates with the sympathetic stimulation of BAT as assessed with MIBG, and with metabolic BAT activity as assessed with FDG (both in lean and obese individuals).

Study design

Observational desigh with invisive measurements

Study burden and risks

Included subjects will visit the AMC hospital on 4 occasions.
Visit 1: Informed consent, medical history, vital signs, laboratory measurements, oral glucose tolerance test, electrocardiogram (ECG). Total blood drawn: 67.5 ml.
Visit 2: 2 hours of cold-exposure, intravenous administration of FDG, measurement of resting energy expenditure and FDG PET-CT
Visit 3: 2 hours of 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.

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.

There is no direct benefit for the volunteers. This study will provide new insights into the activation of BAT. BAT activity has recently been identified as a possible mean to significantly influence glucose metabolism and weight status. However, knowledge on the exact mechanisms that influence BAT activity is scarce. The findings of this study may help us to develop future 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
- Subjects should be able and willing to give informed consent
- 18-40 years old
- BMI range of 19-25 kg/m2 (lean study subjects) or 28-40 kg/m2 (obese study subjects)

Exclusion criteria

- Renal failure (creatinine>135mmol/l)
- Daily use of prescription medication
- 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

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-03-2013
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	01-10-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-08-2013
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	NL41577.018.12