Adaptive Thermogenesis and Obesity - The role of the sympathetic nervous system

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To anwer the question: Is the elevation of energy expenditure and mitochondrial uncoupling smaller in obese than in lean subjects after mild cold exposure and what is the role of the sympathetic nervous system?

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON30502

Source
ToetsingOnline

Brief title
Adaptive thermogenesis and the sympathetic nervous system

Condition

- Metabolism disorders NEC

Synonym
obesity; overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adaptive thermogenesis, energy metabolism, human, sympathetic nervous system

Outcome measures

Primary outcome

Primary study parameters are total daily energy expenditure and mitochondrial

uncoupling

Secondary outcome

N/A

Study description

Background summary

Obesity is an increasing problem in the western society. This study aims at identifying the mechanisms behind the large inter-individual differences in cold-induced adaptive thermogenesis. This leads to an increased insight in the development and treatment of obesity.

Study objective

To anwer the question: Is the elevation of energy expenditure and mitochondrial uncoupling smaller in obese than in lean subjects after mild cold exposure and what is the role of the sympathetic nervous system?

Study design

Subjects will stay twice for 84 hours in the respiration chamber of the department of Human Biology in which 24h Energy Expenditure is measured under standardised conditions. The first 36 hours of the stay will be at an environmental temperature of 22°C, the last 48 hours at 16°C. At the end of each visit three tubes of venous blood and a muscle biopsy will be taken. In one of the stays, subjects will not undergo any pharmacological intervention, in the other stay the subjects will be administred the beta-blocker propranolol. Two visits will be seperated by at least 14 days. In between, a body composition measurement will be carried out for standardisation purposes. From the muscle biopsies changes in gene expression, protein expression, and

mitochondrial respiration will be determined. From the fat biopsies, the amount of the protein PRDM16 will be determinded.

Intervention

see study design

Study burden and risks

All measurement are easy to undergo and there are no extra riscs. Taking the biopsies might cause local bruises. The main load for the subjects is the time consumed by the study, two times 84 hours in the respiration chamber.

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

BMI between 18.5 and 25 or BMI between 30 and 40

Exclusion criteria

diabetes mellitus, hypertension, cardiovascular diseases

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-04-2007
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	isoprenalinsulfate
Generic name:	isoprenalin
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	propranololi hydrochloridum retard PCH
Generic name:	propranolol
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-01-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-01-2007
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	06-09-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-09-2007
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
EudraCT	EUCTR2007-000100-32-NL
CCMO	NL15068.068.07