How to activate your lazy fat? - The role of physical fitness in changing endocrine function of fat tissue in humans

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1a. Compare fat endocrine function in obese fit versus obese unfit people under resting conditions and immediately after exercise.1b. Compare fat endocrine function in non-obese fit versus non-obese unfit people under resting conditions and...

Ethical review	Not approved
Status	Will not start
Health condition type	Endocrine and glandular disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON40189

Source
ToetsingOnline

Brief title
Physical fitness and endocrine function of fat tissue

Condition

- Endocrine and glandular disorders NEC
- Protein and amino acid metabolism disorders NEC

Synonym
Obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adipokines, Obesity, Physical Fitness

Outcome measures

Primary outcome

Our main outcome parameter is fat endocrine function (i.e. fat biopsy and subsequent analysis of expression level of adipokines, and measurement of circulating adipokine levels).

For aim 2, we will also examine metabolic function (glucose and insulin levels) and cardiovascular function (brachial artery flow-mediated dilation, carotid intima-media thickness).

Secondary outcome

Secondary outcome parameters relate to body composition (fat percentage+distribution), physical activity level (measured using an activity monitor), maximal oxygen consumption (measured as peak oxygen consumption during an incremental cycling test), and traditional biomarkers in blood for metabolic and cardiovascular risk (e.g. cholesterol, hs-CRP, HbA1c).

Study description

Background summary

Obesity is a major modifiable risk factor for cardiovascular and metabolic diseases, and is strongly associated with morbidity and mortality. Large epidemiological studies demonstrated that obese individuals with a higher physical fitness or physical activity levels are more likely to have a metabolic and cardiovascular healthy phenotype.1-3 However, these beneficial effects of fitness and training cannot be simply explained by a reduction in the amount of fat tissue.
Recently, it has been suggested that exercise training may alter the adipose

tissue endocrine function, whilst also acute exercise impacts upon adipose tissue endocrine function. Adipose tissue has the capacity to secrete bioactive proteins (adipokines) that may play a crucial role in the pathogenesis of the metabolic syndrome. Obesity is associated with alterations in the secretions of adipokines.4, 5 Therefore, the first aim of this project is to compare endocrine function between obese/non-obese fit and unfit people under resting conditions and immediately after a bout of exercise.
Previous studies found that the measure of the quantity of fat (fat percentage, body mass index, waist-hip-ratio) is related to metabolic and cardiovascular risk. However, little is known whether fat endocrine function is related to metabolic (i.e. insulin resistance) and cardiovascular risk in obesity. Therefore, the second aim is to explore the potential presence of a correlation between endocrine function, metabolic and cardiovascular function.

Study objective

1a. Compare fat endocrine function in obese fit versus obese unfit people under resting conditions and immediately after exercise.
1b. Compare fat endocrine function in non-obese fit versus non-obese unfit people under resting conditions and immediately after exercise.
2. Explore the correlation between endocrine function, metabolic function and cardiovascular risk in obese/non-obese fit/unfit people

Study design

Single-centre cross-sectional study

Study burden and risks

Fat endocrine function. Performance of a subcutaneous fat biopsy is not associated with an important health risk. The procedure may cause some discomfort for the subject when taking the biopsy. However, local anaesthesia will be applied and subjects will be informed about the procedure.
Metabolic function. For this procedure, we will take a venous blood sample to examine glucose and insulin. This is associated with a 5% chance of developing a hemorrhage, which will not result in functional limitation and will resolve within 2 weeks. This venous puncture will also be used to draw blood to assess circulating markers for endocrine and cardiovascular function.
Cardiovascular function. We will adopt non-invasive echo-Doppler to examine endothelial function in the brachial artery and intima media thickness in the carotid artery. This procedure is not associated with potential health risks.
Cycling test and acute exercise intervention. Performance of exercise in healthy individuals or in those with an increased cardiovascular risk is not associated with an important health risk. Nonetheless, we will ensure close supervision of the subject according to our standard operating procedures to perform exercise testing.

Patient benefit. Subjects will not gain a direct health benefit.

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

- * 18 years of age
- Mentally able/allowed to give informed consent

Exclusion criteria

See pages 16 and 17 of the researchprotocol.
- Severe cardiopulmonary disease (as stated in the SOP Exercise testing)

- Orthopedic and/or neurological diseases that impair exercise (as stated in the SOP Exercise testing)
- Anticoagulant therapy (i.e. acenocoumarol, marcoumar)
- Lidocaine allergy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	72
Type:	Anticipated

Ethics review

Not approved

Date:	13-02-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL47379.091.13