Physical activity and abdominal subcutaneous adipose tissue biology in middle-aged lean and obese individuals

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

Summary

ID

NL-OMON32843

Source ToetsingOnline

Brief title Physical activity and biology of adipose tissue

Condition

• Diabetic complications

Synonym total energy expenditure

Research involving Human

Sponsors and support

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

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Intervention

Keyword: Biology of adipose tissue, Physical activity

Outcome measures

Primary outcome

The primary objective of the proposed study is to investigate the level of physical activity among lean and obese middle-aged individuals. We hypothesize that the level of physical activity among healthy (obese) subjects is higher than in patients with type 2 diabetes mellitus.

Secondary outcome

Furthermore, we hypothesize that obese and lean individuals differ with respect

to smaller adipose tissue cell size, lower inflammatory markers and fat

hormones expression (i.e. hsCRP, IL6/18 and leptin) in subcutaneous adipose

tissue compared to patients with type 2 diabetes mellitus (prior to the start

of insulin therapy).

Study description

Background summary

Insulin therapy is frequently needed to achieve adequate glycaemic control in type 2 diabetes mellitus (T2DM), but often at the expense of weight gain. Insulin-associated weight gain is obviously undesirable in an already overweight population and may negatively affect blood pressure, lipid levels, inflammatory and fibrinolytic parameters, adipocytokines and also deter further optimization of insulin therapy. It is unknown what determinants predict insulin-associated weight gain in type 2 diabetes mellitus. Recently, a prospective study (CMO study no. 2008/237) started to investigate determinants of insulin-associated weight gain. One determinant of weight gain is (change in) physical activity. Fagour et al.1 showed that after short-term insulin therapy (4 days) resting energy expenditure decreased which might contribute to weight gain. It is hypothesized that patients who show (pronounced) weight gain after start of insulin therapy (*gainers*) perform less total physical activity after initiation of insulin therapy than patients with less or non weight gain (*non-gainers*). The primary aim of this study is to detect an association between (change in) total physical activity and insulin-associated weight gain.

Furthermore, changes in abdominal subcutaneous adipose tissue will occur during insulin treatment. It is appreciated that fat cell enlargement and increase in adipocytokines production is associated with obesity/weight gain and insulin resistance 2,3. To what extent exogenous insulin itself and the concomitant increase in body weight influences adipocyte size and adipocytokines remains unknown. The secondary aim of the prospective study is to study changes in adipose tissue biology after start of insulin therapy and the relationship with weight gain.

While the prospective study will reveal (changes in) physical activity in patients with type 2 diabetes, it cannot reveal whether the levels of physical activity in these patients differ from those of healthy (obese) subjects. Comparing baseline levels of physical activity and adipose tissue biology in patients starting insulin to healthy (obese) subjects will provide more insight in the level of abnormalities between the two groups. Furthermore, after insulin therapy the change in physical activity and change in metabolic markers of adipose tissue can be compared to baseline levels of these variables in healthy (obese) subjects.

Therefore, we would like to investigate the relationship between physical activity and abdominal subcutaneous adipose tissue biology among men and women with varying body mass index compared to patients with type 2 diabetes mellitus at baseline and after start of insulin therapy. This will enable us to compare patients with diabetes to weight-matched non-diabetic subjects but also with age-matched lean subjects.

Study objective

The primary objective of the proposed study is to investigate the level of physical activity among lean and obese middle-aged individuals. We hypothesize that the level of physical activity among healthy (obese) subjects is higher than in patients with type 2 diabetes mellitus.

Study design

Case-control study (combining data of prospective study CMO nr. 2008/237)

Study burden and risks

Except for abdominal adipose tissue biopsy and venapuncture, all the examinations are non-invasive.

Contacts

Public Universitair Medisch Centrum Sint Radboud

postbus 9101 6500 HB Nijmegen NL **Scientific** Universitair Medisch Centrum Sint Radboud

postbus 9101 6500 HB Nijmegen NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Men and women
- Age: 40-65 years
- Body mass index: 20-25 kg/m2 and 27-35 kg/m2

Exclusion criteria

- Body mass index < 20 or >35 kg/m2
- patients with metabolic syndrome or type 2 diabetes mellitus
- pregnancy or the intention to becom pregnant

Study design

Design

Study type: Observational invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2010
Enrollment:	72
Туре:	Actual

Ethics review

Approved WMO	
Date:	20-01-2010
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

ССМО

ID NL29908.091.09