The effect of activity on insulin sensitivity and lipid metabolim in sedentary people.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON36677

Source
ToetsingOnline

Brief title
NEAT and insulin sensitivity.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
high glucose levels, insulin resistance

Research involving
Human

Sponsors and support

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

Intervention

Keyword: exercise, insulin sensitivity, lipid metabolism, NEAT

Outcome measures

Primary outcome

The change in

- glucose

- insuline

of the activity program walking compared to sitting, and the activity program

sitting/biking compared to sitting.

Secondary outcome

- Area under the curve of glucose and insuline of the activity program walking

compared to sitting, and the activity program sitting/biking compared to

sitting.

- Total cholesterol, HDL, LDL, triglyceriden, apoB en apoA of the activity

program walking compared to sitting, and the activity program sitting/biking

compared to sitting.

- The amount of minutes sitting/ walking/ standing per day per activity program

- Energy expenditure per day per activity program

Study description

Background summary

Inactivity or the lack of physical activity have many negative effects on several diseases, and could even cause diseases related to decreased energy expenditure. Nowadays, the importance of physical activity and exercise are emphasized in the literature and media. However, research recently published

shows that activities associated with everyday activities such as working in and around the house, standing and walking, have a much greater role in energy expenditure than exercise. These everyday activities are summarized as Non Exercise Activity Thermogenesis (NEAT).

Study objective

The effect of NEAT or inactivity on insulin sensitivity and lipid metabolism is unclear. The objective of the present study is to evaluate the effect of 4 days of mainly sitting, or sitting and walking, or sitting, walking and biking on glucose and insulin concentrations in healthy volunteers. Literature shows that 4 days of inactivity is sufficient to see changes in glucose metabolism.

Study design

Intervention

Intervention

The volunteers will follow 3 times a certain activity program for 4 days. These activity programs are:
- Sitting: 14 hours sitting, 2 hours of everyday activities (standing and walking), 8 hours of sleeping or laying down per day.
- Walking: 4 hours waking with normal speed, 8 hours sitting, 2 hour standing, 2 hours of everyday activities (standing and walking), 8 hours of sleeping or laying down per day.
- Sitting/sporting: 13 hours sitting, 1 hour biking, 2 hours of everyday activities (standing and walking), 8 hours of sleeping or laying down per day.
The volunteers will wear two accelerometers during these days, so we can measure their activities more accurate. The CSA Actigraph accelerometer will be placed on the back, and the ActivPAL on the leg. The volunteers will be requested to take off the CSA Actigraph in the shower and during sleeping, this is not the case for the ActivPAL. The volunteers will also be requested to note their activities and thier diet in a diary.
After every 4 days of the activity program, an oral glucose tolerance test will be performed in the moring of the next day (day 5). Before and 15, 30, 45, 60, 90, and 120 minutes after the ingestion of 75 gram of glucose in water, blood will be drawn for measurements of glucose and insulin. Only at baseline, blood will be drawn to measure cholesterol, HDL, LDL, triglycerides, apoB and apoA. These blood draws will be done using a small catheter inserted into the antecubital vein. In total, 73 mL of blood will be drawn with each OGTT. The OGTT will be done 3 times. At the same day, height, weight and circumference will be measured.

Study burden and risks

The oral glucose tolerance test will be performed 3 times. There is a small risk of getting a bruise after the catheter insertion, fainting and vomiting. Biking: at 4 days, subjects will be biking 2 x 30 min. This can possibly cause muscle pain and fatigue during 1-2 days.

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

- Person, 18-60 years old
- BMI 20.0 - 30.0 kg/m2
- Exercise: maximum 1 hour/ week, <= 2x/week; (in the past 3 months)

Exclusion criteria

- Cardiovascular diseases
- Known diabetes mellitus type 1 and 2 or fasting glucose > 6.9 mmol/L
- Other diseases that make physical activity difficult
- Alcohol, a mean of > 2 consumptions/day (in the past 3 months)
- Illegal drug use and cannabis use (in the past 3 months)
- Medication use, other than contraception (in the past 3 months)
- Triglycerides > 3.0 mmol/L

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	23
Type:	Actual

Ethics review

Approved WMO

Date:	12-11-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	08-04-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-06-2011
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
CCMO	NL32900.068.10
Other	volgt