Vascular function markers: differences between lean and abdominally overweight / obese men and effects of weight loss

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The main objectives of this study are:To obtain insight into differences in VF markers between lean and abdominally overweight / obese men.To study cross-sectional relationships between VF markers.To determine the effects of weight-loss in…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lipid metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON39694

Source
ToetsingOnline

Brief title
Body Weight and Vascular Function

Condition

- Lipid metabolism disorders

Synonym
Insulin Resistance Syndrome, Metabolic Syndrome, Syndrome X

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: TI Food and Nutrition

Intervention

Keyword: Body Weight, Obesity, Vascular Function Markers, Weight Loss

Outcome measures

Primary outcome

Parameters related to in vivo VF markers will be studied.

The primary endpoint is the difference in flow mediated dilation (FMD) of the brachial artery

- between lean and abdominally overweight / obese male subjects.

- in abdominally overweight / obese men after weight-loss due to restriction of energy intake

Secondary outcome

Secondary endpoints are differences in * and relations between * other VF measurements and of plasma biomarkers related to low-grade inflammation and vascular activity

- between lean and abdominally overweight / obese male subjects

- in abdominally overweight / obese men after weight-loss dure to restriction of energy intake

- during the fasting and postprandial / hyperinsulinemic state

Study description

Background summary

An increased body mass impairs vascular function (VF), an important characteristic of subjects suffering from type 2 diabetes and a risk marker for cardiovascular diseases. However, a wide variety of in vivo VF markers exists each measuring different aspects of VF. Each of these markers addresses a different aspect of the vasculature. Studies comparing under standardized conditions the differences and relationships of the many different VF measurements in lean and abdominally overweight / obese subjects are missing. Also, there is a great need to know which of these markers are sensitive to dietary challenges.

Study objective

The main objectives of this study are:

To obtain insight into differences in VF markers between lean and abdominally overweight / obese men.
To study cross-sectional relationships between VF markers.
To determine the effects of weight-loss in abdominally overweight / obese men on VF markers during the fasting and postprandial state.
To determine the effects of weight-loss in abdominally overweight / obese men on VF markers during the fasting and hyperinsulinemic state.
To study in abdominally overweight / obese men relationships between changes in VF markers after weight-loss.

Study design

At baseline, lean and abdominally overweight / obese male subjects have to attend on two days the research facilities to perform the VF measurements. Measurements will be performed during the postprandial phase and during a hyperinsulinemic clamp. The abdominally overweight / obese men will then be randomly assigned to a weight-loss program or to a no-weight loss (*control*) treatment. After this period, measurements will be repeated. After these measurements, subjects from the control group will be given the possibility to loose weight using the same weight-loss program, but without any measurements.

Intervention

Lean subjects will only be studied cross-sectionally, and obese / overweight subjects before and after random assignment to a weight-loss intervention. Subjects assigned to the energy-intake restricted weight-loss intervention will consume a very-low energy diet between 4-5 weeks providing 2.1 MJ/day. Once the

waist circumference within this period is below 102 cm, subjects will consume a mixed solid energy-restricted diet providing 4.2 MJ/day for the following 1 - 2 weeks. Then they will be fed for at least 2 weeks a diet matching their energy requirements (weight-stable conditions). The total intervention period will last 8 weeks. Subjects assigned to the control condition will maintain their habitual diet.

Study burden and risks

Before the start of the study, all subjects will be screened to determine eligibility during a visit of respectively 20 minutes. During this, body weight, height, waist circumference and blood pressure will be measured. In addition, a venous blood sample (5.5mL) will be drawn.

Following screening, all participants will visit our research facilities at Maastricht University Medical Center two times: once for a postprandial test (7 hours) and once for a hyperinsulinemic euglycemic clamp (7 hours). During this period, subjects will remain at the MUMC. In addition, abdominally overweight / obese subjects will visit our research facilities every week during the intervention period, and three times at the end of the intervention period: once for a postprandial test (7 hours), once for a hyperinsulimenic euglycemic clamp (7 hours), and once for fMRI measurements (1 hour). fMRI measurements will be done in 30 overweight / obese subjects. Total time investment for the lean and abdominally overweight / obese subjects will be approximately 885 (14.75 hours) and 1860 (control group) - 1890 (intervention group) minutes (31 - 31.5 hours). fMRI measurements will take 60 minutes (1 hour).

The amount of blood drawn will be 209 mL (5.5 mL during the screening visit, 113.5 mL at the postprandial test day, and 90 mL at the hyperinsulinemic test day) per lean and 412.5 mL per abdominally overweight / obese male subject during the whole study. Therefore, subjects are not allowed to have donated blood 8 weeks prior to participation.

Lean participants will have no direct health benefit from participation, whereas abdominally overweight / obese subjects will be facilitated to loose weight (either as intervention or after completion of the control treatment).

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

- Aged between 18 and 65 years
- Waist circumference below 94 cm or between 102-110 cm
- Caucasian
- Mean plasma glucose < 7.0 mmol/L
- Mean serum total cholesterol < 8.0 mmol/L
- Mean triaclglycerol < 4.5 mmol/L
- Plasma Hba1c < 6.5%
- No current smoker
- No diabetic patients or individuals receiving antidiabetic medication
- No familial hypercholesterolemia
- No abuse of drugs
- Less than 14 alcoholic consumptions per week
- Stable body weight (weight gain or loss <3 kg in the past three months)
- No use of medication known to affect bood pressure, serum lipid or glucose metabolism
- No indication for blood pressure lowering treatment
- No severe medical conditions that might interfere with the study, such as epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- No active cardiovascular disease like congestive heart failure or cardiovascular event, such as an acute myocardial infarction or cerebro vascular accident

- No contra-indications for MRI imaging (e.g. pacemaker, surgical clips/material in body, metal splinter in eye, claustrophobia)
- Willingness to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study, during the study and for 4 weeks after completion of the study
- No difficult venipuncture as evidenced during the screening visit
- Willingness to stop the consumption of vitamins, minerals and (food) supplements from 3 weeks before the start of the study and during the study

Exclusion criteria

- Women
- Non-caucasian
- Mean plasma glucose * 7.0 mmol/L
- Mean serum total cholesterol * 8.0 mmol/L
- Mean triaclglycerol * 4.5 mmol/L
- Plasma HbA1c * 6.5%
- Current smoker, or smoking cessation < 12 months
- Diabetic patients or individuals receiving antidiabetic medication
- Familial hypercholesterolemia
- Abuse of drugs
- More than 14 alcoholic consumptions per week
- Unstable body weight (weight gain or loss > 3 kg in the past three months)
- Use of use of medication known to affect blood pressure, serum lipid or glucose metabolism
- Indication for blood pressure lowering treatment
- No severe medical conditions that might interfere with the study, such as epilepsy, asthma, chronic obstructive pulmonary disease, inflammatory bowel diseases, auto inflammatory diseases and rheumatoid arthritis
- Active cardiovascular disease like congestive heart failure or recent (< 6 months) event, such as an acute myocardial infarction or cerebro vascular accident
- Contra-indications for MRI imaging (e.g. pacemaker, surgical clips/materials in body, metal splinter in eye, claustrophobia)
- Use of an investigational product within the previous 1-month
- Not willing to give up being a blood donor (or having donated blood) from 8 weeks before the start of the study, during the study or for 4 weeks after completion of the study
- Not or difficult to venipuncture as evidenced during the screening visit
- Not willing to stop the consumption of vitamins, minerals o (food) supplements from 3 weeks before the start of the study and during the study

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2012
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	03-09-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	26-09-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	28-03-2014
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	NL41397.068.12