Metabolic and vascular adaptations to a positive energy balance

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22377

Source
NTR

Brief title
Hypercaloric study

Health condition

Insulin resistance, diabetes, obesity and inflammation

Sponsors and support

Primary sponsor: Department of Endocrinology and Metabolism
Academic Medical Center, Amsterdam, the Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

- Weight gain and loss

- Pro-inflammatory response in adipose tissue and in plasma after initialising a hypercaloric diet

- Change in inflammatory response after switching to hypocaloric diet

- Insulin sensitivity; Homa-IR and B-cell function

- Changes in incretine response in relation to hyper- and hypocaloric diet

Secondary outcome

- Changes in symphatic nervous activity

- Glucoregulatory hormones

Study description

Background summary

Since not all obese people develop insulin resistance and the time frame between the onset of obesity and the early onset of the disturbances in lipid, glucose and endothelium metabolism is not exactly known, longitudinal studies, studying the metabolic alterations in response to a positive energy balance in humans are needed.

The present study is a prospective study to evaluate the sequence of metabolic adaptations in lean subjects, during a positive energy balance followed by a negative energy balance.

Study objective

A positive energy balance in male subjects with a first degree relative with DM II will result in a pro-inflammatory response (MCP-1, Il 6 and TNFá) associated with inflammatory changes within adipose tissue (AT) and an increased sympathetic activity. The degree of systemic and local (AT) inflammation will be predictive for the subsequent decrease in hepatic and peripheral insulin sensitivity. The negative energy balance will restore glucose and lipid metabolism to baseline levels preceded by a decrease in inflammatory markers.

Study design

This study will include 8 men who will consume a hyper caloric diet until they gain sufficient amount of weight, defined as 6% of their initial body weight. We expect that the study subjects will reach this target within 2-3 months. If participants have not reached the 6% weight gain within 3 months, the hypercaloric diet will be ended also. The hypercaloric diet will directly be followed by a hypo-caloric diet to return to the baseline weight.

Intervention

Based on the eucaloric diet in the run-in phase, a hypercaloric diet will be designed calculated as 1.4 x kcal in the eucaloric diet. The protein, fat and carbohydrate content of the diet will respectively be 16%, 30% and 54% of the caloric intake. The surplus of energy will be provided as a liquid (Nutridrink) which consists of 12 g protein, 36.8 g carbohydrates and 11.2 g fat (total 300 kcal) per 200 ml. The hypercaloric diet will be ended when study subjects reach 6%weight gain, or after 3 months if participants do not have reached the 6% weight gain.

Thereafter based on the actual REE, the subjects will consume a diet (1.0 x REE) aimed to lose the gained weight and return to baseline weight. Subjects will be monitored weekly for resting energy expenditure, physical activity, weight, body composition and dietary intake. The diet will be adjusted if the weight remains stable. The study will be ended when the participant has lost the gained weight.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 30-50

2. normal glucose tolerance (OGTT)

3. Caucasian men

4. normal weight BMI >20 and <25

Exclusion criteria

1. Age < 30- > 50 years

2. Frequent intensive exercise (>2 week) or sedentary life style

3. Any medication

4. Lipid disorders, renal insufficiency, elevated liver enzymes

5. Obesity in the past

6. BMI < 20->25 kg/m2

7. Smoking

8. Unstable weight 3 months prior to study inclusion

9. High blood pressure

10. Alcohol abuse (> 3day)

11. Participation in research during the year prior to inclusion

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2008
Enrollment:	8
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-10-2008
Application type:	First submission

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
NTR-new	NL1441
NTR-old	NTR1502
Other	: MEC 08/077
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A