Adipogenic capacity as a mediator of weight gain

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This study investigates the differences in response between people with a low/high/medium predisposition towards weight regain (based on their genetic background) to a period of weight reduction followed by weight maintenance in terms of energy…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34907

Source
ToetsingOnline

Brief title
weight gain

Condition

- Other condition

Synonym
corpulence, overweight

Health condition

overgewicht en obesitas

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adipogenic capacity, body composition, energy expenditure, physical activity

Outcome measures

Primary outcome

The difference in energy expenditure, body composition, adipogenic capacity,

physical activity and hormone levels between people with a high/low/medium

predisposition for weight gain (based on their genetisch background) in

response to a period of weigth loss followed by weight maintenance.

Secondary outcome

not applicable

Study description

Background summary

A major problem in the treatment of obesity is the weight regain after weight reduction. It has been shown that a genetic component plays a role in this, since some people have a predisposition towards weight gain in comparison to others. This genetic background is still unclear, although some polymorphisms are found to be associated with obesity and weight gain. This genetic component influences various other factors en could have an effect on energy expenditure, adipogenic capacity and physical activity.

Study objective

This study investigates the differences in response between people with a low/high/medium predisposition towards weight regain (based on their genetic background) to a period of weight reduction followed by weight maintenance in terms of energy expenditure, body composition, adipogenic capacity, physical

acitivity and hormone levels.

Study design

In this study subjects will be assigned to three groups, each with a high, low or medium predisposition for weight gain. This will be based on the FTO allele, with AA, TT and AT respectively (p.17 van het research protocol). These groups will all follow a weight loss period of 2 months followed by a weight maintenance period of 10 months. During this year subjects have to visit the university 6 times (see p. 13+14):

1. screening
2. start weight loss (0)
3. half-way weight loss (1maand)
4. end weight loss (2 maanden)
5. first part weight maintenance (5 maanden)
6. end weight maintenance (12 maanden)

De duration of these test days depends on the group, like described earlier (E2 of p13 + 14 of the research protocol).

Intervention

The diet (modifast) is an intervention of this study. The subjects will follow this diet for 2 months and it consists of 2.1MJ/day as 3 meal subsituting shakes or puddings with fruit en vegetables to get the vitamines.

Study burden and risks

all subjects:
- blood sampling at screening, before diet, after diet, after weight maintenance (risks of minor bruising and pain)
- diet (Modifast)
- completing questionnaires
- measuring weigth, height, waist and hip
- deuterium, urine collection and bodpod measurements
- wearing TracmorD

subjects in group with high/low predisposition:
- fat biopsy (risks of minor bruising and pain)
- stay in respiration chamber overnight
- ventilated hood measurements
- doubly labeld water and urine collection

All subjects visit the university six times. The time burden for each subject depends on whether they belong to the high or low predisposition group or not. For all subjects there is a screening of around 45 minutes. Four visits for the

group with only limited measurements (body weight, waist and hip circumference and body composition) will take 60 minutes and one visit of 20 minutes. In total these subjects need to stay at the university for approximately 305 minutes (=5h). Three visits for the subjects in the groups with a high/low predisposition for weight regain will take one night and the subsequent morning, so approximately 16h. The other two visits will be 20 and 60 minutes. In total these subjects need to stay at the university for approximately 50h. There are no risks for the subjects in consuming the VLED (Modifast, together with the recommended fruit and vegetables) as the macronutrient composition and vitamins/minerals content meet the Dutch recommended daily allowance. This VLED will demand some energy from the subjects at home. However, losing weight is a great advantage for these subjects, so probably they have enough will-power to complete these 2 months VLED. There is a risk of minor bruising during blood sampling. Deuterium is an isotope of water that naturally appears in the body. Drinking it does not expose the subject to any risks. The doubly labelled water is safe to use in humans since the water is labelled with stable isotopes. The concentrations of the samples are with an enrichment of 100 to 200 ppm far below 10000 ppm or 1%, where effects on biological systems have been observed. Collection of urine at home is only a minor time burden for the subjects. Studies in the respiratory chamber will be conducted using standard operating procedures. A pair of subjects will always participate in the study at the same time and therefore they will never be alone. The subjects will be able to contact the investigators during the entire night. In addition, they will be able to get out of the chamber at any time they feel uncomfortable. Taking a fat biopsy will be done under local anaesthetic, which only gives a very brief tingling pain at the site of infiltration under the skin. Local anaesthesia occurs with most standard clinical procedures in which this is used, resulting in minimal risks. Allergies for local anaesthetics will be one of the exclusion criteria. The biopsy itself can give a mild soreness and bruising near the biopsy site. Minimal scarring rarely occurs. Wearing the Tracmor will not have any risk or burden.

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

healthy males and females
overweight (BMI 28-35)
18-50 years of age

Exclusion criteria

BMI <28 or >35
age <18 or >50
allergies (for certain foods/local aneasthetics)
smoking
restrained eaters (TFEQ; F1>9)
use of medication (except oral contraceptive)
pregancy or breastfeeding
instable weight (>5kg weight loss/gain in 3 months prior to study)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-07-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	11-01-2010
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-09-2010
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	NL30673.068.09
Other	nog onbekend