An adipocyte-driven mechanism for weight regain after weight loss: the yo-yo effect

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Primary Objective: To investigate the association between the weight-loss-induced cellular stress response and the rate of weight regain. Secondary Objective: To investigate the difference in cellular stress response and weight regain after rapid…

Ethical review	Approved WMO
Status	Pending
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON37833

Source
ToetsingOnline

Brief title
ADIPOSTRESS

Condition

- Appetite and general nutritional disorders

Synonym
adiposity, obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: adipocyte stress, obesity, weight cycling

Outcome measures

Primary outcome

The association between the amount of weight regain after the weight loss period and changes in adipokines, parameters of adipocyte metabolism, in vivo adipose tissue metabolism, adipocyte extracellular matrix gene expression profiles, adipocyte stress protein expression and gene polymorphisms in selected genes.

Secondary outcome

The difference in weight regain and associated parameters between rapid and slow weight loss regimens.

Study description

Background summary

Almost half of the Dutch population is currently characterized by overweight and obesity. Losing weight is not the problem in obesity treatment, it is the seemingly obligatory weight regain after weight loss: the yoyo-effect. We hypothesize that weight loss-induced cellular stress in adipocytes leads to production of signals by the stressed adipocyte that counteract their stress by changing metabolism and caloric intake, resulting in weight regain.

Study objective

Primary Objective: To investigate the association between the weight-loss-induced cellular stress response and the rate of weight regain.
Secondary Objective: To investigate the difference in cellular stress response and weight regain after rapid and slow weight loss.

Study design

This is a randomized parallel-group human intervention study, comparing to weight loss interventions.

Intervention

Subjects will receive meal replacements, replacing either all or part of the daily meals, during the intervention period. The first group will consume a 500 kcal/d diet for 5 weeks while the second group consumes a 1250 kcal/d diet for 3 months, both followed by 1 week normalization and a 2 week strict weight maintenance diet. During the 9 month follow-up period subjects will receive dietary advice according to the Dutch recommendations for healthy eating.

Study burden and risks

Subjects will follow an energy-restricted diet for 5 weeks to 3 months and will undergo a number of tests with minor risks. To assess adipose tissue PO2 a microdialysis probe will be inserted in the anesthetized subcutaneous adipose tissue two times. Furthermore, a radioactive tracer (13Xe) will be injected to assess adipose tissue blood flow, with a radioactivity that is equal to about one-fiftieth the amount of a chest x-ray (four times). Also, fat percentage will be measured using the Bod Pod. Throughout the study, ten breath samples will be collected in a 5 liter plastic bag. These measurements are completely painless and will take about 5 minutes . In vivo adipose tissue metabolism will be studied after ingestion of a high-fat meal enriched with a stable isotope tracer ([U-13C] palmitic acid) (2 times). This technique also requires the cannulation of an epigastric vein and a superficial dorsal hand vein. Adipose tissue biopsies are taken from the abdominal subcutaneous adipose tissue by an experienced researcher at Maastricht University (4 times). The biopsies will be collected under local anaesthesia using the needle biopsy technique. A total volume of 770 ml blood will be collected during the entire study period of 11-13 months. Finally, subjects will complete habitual physical activity questionnaires and 3-day food diaries (4 resp 3 times). Subjects will potentially benefit from this study via a reduction in risk factors for cardiovascular diseases due to weight loss. In addition they will receive advice on healthy eating habits from a dietician.

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 volunteers aged 20-65 y, BMI 28-35 kg/m2, non-smokers

Exclusion criteria

Subjects using prescription medication, or suffering from diseases or conditions that might influence the outcome of the study: this concerns diseases/medication that influence body weight regulation (malabsorption, untreated hypo/hyperthyroidism, eating disorders, systemic use of steroids, etc.) and obesity-related cardiovascular risk factors (heart disease, systolic and diastolic blood pressures > 160/100 mmHg, blood glucose > 6.1 mmol L-1, blood cholesterol > 7 mmol L-1, blood triglycerides > 3 mmol L-1), marked alcohol consumption > 21 alcoholic units week-1 (male), or >14 alcoholic units week-1 (female), planned major changes in physical activity during the study to an extent that might interfere with the study outcome, as judged by the investigator; blood donation within the past 2 months prior to the study; weight change of >3 kg within 2 months prior to the study; psychiatric disease (based on medical history only); pregnant or lactating women, or women planning to become pregnant within the next 12 months; surgically treated obesity; participation in other clinical studies within the last 3 months; drug abuse (based on clinical judgment); unable to give informed consent; unable to engage in a low-calorie diet; following a special diet (e.g. Atkins).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-02-2012
Enrollment:	58
Type:	Anticipated

Ethics review

Approved WMO Date:	15-02-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-04-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-12-2012
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	NL38099.068.11