Dietary protein requirements and caloric over-consumption on unbalanced diets

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To determine ad libitum daily energy intake, energy balance and appetite profile in response to protein/carbohydrate and fat ratio over 12 consecutive days, and in relation to age, gender, BMI and FTO polymorphisms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON36029

Source
ToetsingOnline

Brief title
Dietary protein requirements on unbalanced diets

Condition

- Metabolism disorders NEC

Synonym
obesity, severe overweight

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Energy intake, Protein leverage hypothesis, Protein requirement, Satiety

Outcome measures

Primary outcome

The primary endpoints of this study are energy intake, energy balance and

appetite profile over 12 consecutive days.

Secondary outcome

n.v.t.

Study description

Background summary

Following the protein leverage hypothesis, energy intake may be a derivative of protein intake. Therefore, in response to an unbalanced menu relative to the usual daily intake target, protein intake should be prioritized. Individuals may over-consume carbohydrate and fat of a menu containing a lower ratio of protein to carbohydrate and fat until the daily intake target amount of protein is ingested, and not the target of total energy intake because of a deficit of protein intake. In contrast, individuals may under-consume energy when the menu has an increased protein to carbohydrate and fat ratio. The protein leverage hypothesis requires evidence for why protein intake is more important than carbohydrate or fat in relation to food intake regulation.

Study objective

To determine ad libitum daily energy intake, energy balance and appetite profile in response to protein/carbohydrate and fat ratio over 12 consecutive days, and in relation to age, gender, BMI and FTO polymorphisms.

Study design

The study will be conducted in a crossover design with three randomly sequenced conditions.

Intervention

Subjects will consume breakfast, lunch and dinner ad libitum in the lab, for 12 days per condition (three conditions: protein intake of 5, 15 and 30 energy percent). Snacks will be provided in boxes for consumption at home. Daily total energy intake will be measured, as well as hunger and satiety before and after each meal. Body weight will be measured to assess energy balance, and 24-hour urine nitrogen content to confirm protein intake. FTO polymorphisms will be determined in order to determine the interaction of the genetic background of the obesity related gene FTO and changes in energy intake.

Study burden and risks

The study does not include any major risk for the subjects. Anthropometric and body composition measurements, performed during the screening, will not be invasive for the subjects. Blood sampling is limited to one sample per subject. There are no side effects, except from a minor risk of bruising. Urine sampling will be done in urine bottles added with diluted HCl, which might pose a risk for the subjects. However, subjects will be carefully instructed how to handle the bottles to reduce these risks. Additionally, there are no risks for the subject in consuming any of the provided meals, because people with certain food allergies are excluded for participation and all food items will be commercially available in normal Dutch supermarkets. This study does not have any benefits for the subjects themselves, but will give possible new knowledge for the treatment of obesity.

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, age 18-70 y, BMI 18-35 kg/m2, non-smoking, weight stable

Exclusion criteria

Smoking, use of medication, more than moderate alcohol consumption

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-05-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	16-05-2011
Application type:	First submission
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
ClinicalTrials.gov	NCT01320189
CCMO	NL36167.068.11