Effects of beef protein consumption on energy intake - The protein leverage hypothesis

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

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

Summary

ID

NL-OMON36886

Source
ToetsingOnline

Brief title
Effects of beef protein consumption on energy intake

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,National Cattlemen's Beef Association

Intervention

Keyword: Beef protein, Energy intake, Protein leverage hypothesis, Satiety

Outcome measures

Primary outcome

The primary endpoint of this study is energy intake over 12 consecutive days.

Secondary outcome

The secondary endpoints of this study are body weight changes and appetite

profile over 12 consecutive days.

Study description

Background summary

The protein leverage hypothesis requires specific evidence whether energy intake would depend on a possible protein intake target in humans. Meat protein as complete protein may show most beneficial effects on variables regarding food intake regulation.

Study objective

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

Study design

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

Intervention

The study will be performed using diets containing 5 energy percent from protein (low protein), 15 energy percent (normal protein) and 30 energy percent (high protein). Beef protein will be used as main meat protein source in the normal protein and high protein conditions. Subjects will consume breakfast, lunch and dinner ad libitum in the research restaurant, for 12 consecutive days

in each of the protein-content conditions. Snacks will be provided in boxes for consumption at home. 24-hour urine nitrogen content will be determined to confirm protein intake. Energy intake, macronutrient intake, body weight, and appetite profile will be measured. FTO gene alleles 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 largest disadvantage of this study is the required time for daily visiting the University for the consumption of the meals. Test days will be scheduled in agreement with the subjects, and during normal times for breakfast, lunch and dinner to reduce strain on the subjects. The time investment will be maximal 5 hours per day.
There are no risks for the subjects in consuming any of the provided meals and snacks, because people with certain food allergies are excluded for participation and all food items will be commercially available in normal Dutch supermarkets. Except for the provided meals and snacks, subjects are only allowed to consume water, tea and coffee without milk and sugar. No other foods or beverages are allowed during the test periods. However, a variety of food items will be provided to prevent for one-sidedness during the test periods, and subjects will always receive freshly prepared meals, without doing any efforts as shopping or cooking. During the screening the liking of the provided food items will be checked, and people who will not like the foods will be excluded from participation in the study.
Anthropometric 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.
This study does not have any benefits for the subjects themselves, but will give possible new knowledge for the treatment of obesity. The researchers are aware that participation in the study is a great burden for the subjects, and will express their sympathy. Subjects will be carefully treated, and their well-being will be evaluated daily.

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

BMI 18-35 kg/m2
Age 18-70 years
Healthy (absence of disease)
Non-smoking
Not using a more than moderate amount of alcohol (> 10 consumptions/wk)
Being weight stable (weight change < 3 kg during the last 6 months)
Not using medication or supplements except for oral contraceptives in women

Exclusion criteria

Not healthy (presence of disease)
Smoking
Using a more than moderate amount of alcohol
Not being weight stable
Using medication or supplements except for oral contraceptives in women
Not meeting the criteria for BMI and age
Pregnant or lactating
Allergic for used food items

Vegetarian

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-10-2012
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	NCT01646749
CCMO	NL41371.068.12