Energy expenditure and sleep in response to protein/carbohydrate and fat ratio

Published: 12-03-2012
Last updated: 01-05-2024

To determine energy expenditure and sleep in response to protein/carbohydrate and fat ratio of the diet over a short-term and long-term period of time.

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

Summary

ID

NL-OMON37867

Source
ToetsingOnline

Brief title
Energy expenditure, sleep and macronutrients

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: Carbohydrate, Energy expenditure, Protein, Sleep

Outcome measures

Primary outcome

The primary endpoints of this study are energy expenditure, substrate oxidation and sleep.

Secondary outcome

The secondary endpoints of this study are body composition, fat distribution, muscle protein synthesis rate, expressed as fractional synthetic rate (FSR) and whole body protein turnover.

Study description

Background summary

The prevalence of obesity has increased worldwide to epidemic proportions. For long-term treatment success permanent lifestyle changes are necessary with regard to approach to food, physical activity patterns and behavior to emotional stress. Moreover, an association has been shown between sleep disturbance and obesity.
Weight loss strategies regarding food intake regulation mainly focused on changing patterns of fat and carbohydrate consumption during the last decades. The role of protein has largely been ignored. However, protein has been observed to increase satiety and energy expenditure to a greater extent than carbohydrate and fat and can therefore reduce energy intake. However, it still has to be confirmed if this effect is permanent or transient over a longer period of time. Moreover, dietary intakes may significantly affect sleep when macronutrient intakes are manipulated. Since sleep deprivation has been recognized as a risk factor for obesity, improving sleep by a change in macronutrient intake would be promising in the treatment of obesity.

Study objective

To determine energy expenditure and sleep in response to protein/carbohydrate

and fat ratio of the diet over a short-term and long-term period of time.

Study design

The study will be conducted in a parallel design. Allocation of subjects to the two conditions is randomized.

Intervention

The subjects will stay three times 48 hours in the respiration chamber: at baseline, after 1 week (short-term effect) and after 12 weeks (long-term effect) of dietary intervention. After baseline (protein intake of 15 En%), two conditions will be applied: protein intake of 5 and 30 energy percent. Fat content will be kept constant.

Study burden and risks

This study does not include major risk factors for the subjects. Blood sampling in this study is limited and without side effects, except from a minor risk of bruising. Deuterium is an isotope of water that naturally appears in the body. Drinking it does not expose the subject to any risks. 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 on 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. A 30En% protein or a 5En% protein diet for 12 weeks will not have any side effects on the subject*s health. 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. The experiment will take about 162 hours of the subject*s time. Insertion of the catheters in a vein is comparable to venapunction and here as well the only risk is a small local hematoma. This is the same for the muscle biopsy. The incision made for obtaining the muscle biopsy will be done by an experienced physician and will heal completely. The research group of Prof. Dr. L. van Loon has extensive experience with taking muscle biopsies. During the follow up several days after taking the biopsy no complications have been reported.
The test beverages contain tested normal nutritional ingredients and for this reason do not form any health risks. The labeled amino acids tracers applied in this experiment are not radioactive and are completely safe. The production of the tracers for intravenous administration will occur in a sterile environment according to GMP guidelines.
This study does not have any benefits for the subjects themselves, but will

give possible new knowledge for the treatment of obesity.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6200 MD
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6200 MD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Healthy, age 18-35 y, BMI 18-27 kg/m2, non-smoking, weight stable, no sleeping problems, estimated glomerular filtration rate >= 90ml/min/1.73m2

Exclusion criteria

Smoking, use of medication, sleep problems, more than moderate alcohol consumption, estimated glomerular filtration rate < 90ml/min/1.73m2

Exclusion criteria for MRI (electronic implants, pacemakers, metal fragments in the eyes, skin or body)
For muscle protein synthesis measurement, all co-morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthrosis, arthritis, spasticity/rigidity, all neurological disorders and paralysis), use of anticoagulants, blood diseases, allergy for lidocain, use of gastric acid inhibitors.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2012
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	12-03-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	19-09-2012
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
ClinicalTrials.gov	NCT01551238
CCMO	NL39152.068.11