The effects of orally and intraduodenally administered pea protein on satiety parameters in vivo in lean and obese subjects.

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In this study we will be looking at the effects of the different administration routes on release of satiety hormones by the small intestine.

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

Summary

ID

NL-OMON34022

Source
ToetsingOnline

Brief title
The effects of pea protein on satiety parameters in vivo

Condition

- Appetite and general nutritional disorders

Synonym
Obesitas, overweight

Research involving
Human

Sponsors and support

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

Intervention

Keyword: obesitas, pea protein, satiety

Outcome measures

Primary outcome

We will be looking at the secreted satiety hormones by the biops. We will be looking at CCK, GLP-1, and PYY. We will also look at the hunger and satiety ratings of the subjects

Secondary outcome

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Study description

Background summary

Food in the small intestine stimulates intestinal cells to secrete satiety hormones. These satiety hormones regulate the feeling of hunger and food intake. Little is known about the effects of different administration routes on the release of satiety hormones.

Study objective

In this study we will be looking at the effects of the different administration routes on release of satiety hormones by the small intestine.

Study design

During the first 4 testdays, subject will receive protein or placebo, either oral or intraduodenal administered. On the testdays with oral administration, samples will be taken from the intestinal fluid. Bloodsamples will also be taken. On the last testday, biopsies are taken from the subjects. The tisue is than kept alive for approximately 4 hours. As an optional testdag, biopsies are taken again from the subjects.

Intervention

During the first 4 testdays, subject will receive protein or placebo, either oral or intraduodenal administered. On the testdays with oral administration, samples will be taken from the intestinal fluid. Bloodsamples will also be taken. On the last testday, biopsies are taken from the subjects.

Study burden and risks

A hematome can develop after placing the canula. There is a small chance that intestinal perforation may occur. The test subject can experience some discomfort when the gastroscope is inserted.

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

• Male, non smoking
• Age between 18 and 65 years
• Body Mass Index between 20 and 37 kg/m2
• No medication that could interfere with the test results (e.g. glucose lowering medication)
• No history of intestinal illness
• Stable body weight over the last three months

Exclusion criteria

• Age under 18 and over 65 years
• BMI under 20 and over 37 kg/m2
• Medication or disease that could interfere with the results of the study, to be judged by the responsible medical doctor
• Recent blood donation
• Intestinal illness at any time in the past

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2009
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	22-09-2009
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	NL24018.068.08
Other	NTC1437