Assessment of the effects of gastric degradation-protected pea protein extract on mucosal satiety hormone release by human duodenal tissue

Published: 20-02-2013
Last updated: 23-04-2024

To assess the degradability of five different protected pea protein products by human gastric fluid, and to assess the effects of different protected pea protein extracts on the intestinal satiety hormone release.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38483

Source
ToetsingOnline

Brief title
Protected pea protein extract and satiety hormone release

Condition

- Other condition
- Appetite and general nutritional disorders

Synonym
Obesity, overweight

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: BioActor BV,industrie

Intervention

Keyword: pea protein, satiety hormone, ussing chamber

Outcome measures

Primary outcome

The primary endpoint is the effect of five different protected pea protein

extracts on intestinal satiety hormone release (CCK, GLP-1, PYY).

Secondary outcome

Secondary endpoint is the degradability of the different prototypes by human

gastric fluid, tested in an in vitro setting.

Study description

Background summary

The increasing prevalence of overweight and obesity among the population contributes to increased incidences of chronic metabolic diseases. Healthcare costs related to these diseases are rising; prevention or delay of onset of disorders associated with overweight is needed. Food ingestion exerts a transient suppressive effect on appetite and further food intake by releasing gastrointestinal hormones. Proteins have been shown to be more satiating than carbohydrates and fat. Intraduodenal administration (via a naso-duodenal intubation) of pea protein has been shown to reduce food intake and increase satiety hormone levels in humans, in contrast to orally dosed (unprotected) pea protein. In the present study we aim to investigate the effects of human gastric fluid on the degradability of five different protected pea protein products. Further, in an ex vivo experiment on freshly obtained human duodenum tissue applying Ussing chamber technology, we aim to investigate the intestinal satiety hormone release by the five different prototypes. The prototype that is

less degraded by human gastric fluid and is most effective in intestinal satiety hormone release will be used in a future clinical trial.

Study objective

To assess the degradability of five different protected pea protein products by human gastric fluid, and to assess the effects of different protected pea protein extracts on the intestinal satiety hormone release.

Study design

In vitro gastric fluid experiment and ex vivo Ussing chamber experiment.

Intervention

Participants will have to visit the study site once. For the gastric fluid experiment the participant will receive a nasogastric catheter and about 75 mL gastric fluid will be aspirated. On another occasion, a gastroduodenoscopy tissue will be performed to obtain duodenum tissue samples for the Ussing chamber experiments.

Study burden and risks

There are several burdens volunteers can experience during this study. After the screening visit, participants will have to invest approximately 1 hour in the study. They will have to visit the MUMC+ in total 2 times. Furthermore, a subject that participates in the gastric fluid experiment will receive once a nasogastric catheter. The risk of stomach perforation is generally considered as nil. The subjects will perceive mild discomfort during the placement of the catheter. For the Ussing chamber experiment, a gastroduodenoscopy will be performed and biopsies will be taken. This procedure bears a small risk (<0.0002%) risk of bowel perforation and bleeding at the biopsy sites in general clinical use, however the risk in the present study is expected to be much smaller, because instead of patients, healthy subjects without intestinal disease will be investigated.

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

Men/women, healthy human beings, age 18-70 years, BMI between 18.5 and 24.9 kg/m2, consistently stable body weight for at least 6 months (+/- 2 kg)

Exclusion criteria

Type 2 diabetes mellitus (defined as fasting plasma glucose >= 7.0 mmol/L); Gastroenterological diseases or abdominal surgery (uncomplicated appendectomy, cholecystectomy and hysterectomy allowed, and other surgery upon judgment of the principle investigator); Cardiovascular diseases, cancer, liver or kidney malfunction, auto-immune diseases, disease with a life expectancy shorter than 5 years; Abuse of products; alcohol (>20 alcoholic consumptions per week) and drugs; Smoking; Plans to lose weight or following a hypocaloric diet; Use of any medication, including vitamin supplementation, except oral contraceptives, within 14 days prior to testing; Regular use of laxation products; Use of antibiotics in the 90 days prior to the start of study. Administration of investigational drugs or participation in any scientific intervention study which may interfere with this study (to be decided by the principle investigator), in the 90 days prior to the study; Known pregnancy, lactation (checked by a pregnancy test before start of study); Blood donation within 3 months before study period; Self-admitted HIV-positive state

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	25-02-2013
Enrollment:	31
Type:	Anticipated

Ethics review

Approved WMO

Date:	20-02-2013
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
CCMO	NL42988.068.13
Other	Volgt, registratie in clinicaltrials.gov