The effect of repetitive ileal brake activation on food intake, satiety, gastrointestinal peptide release, gastric emptying and gallbladder volume

Published: 23-10-2014
Last updated: 22-04-2024

Aim: To determine the effect of repetitive ileal brake activation on food intake, satiety, gastrointestinal peptide release (CCK, GLP-1, PYY, glucose and insulin) and gut motilityHypothesis: We hypothesize that after repetitive ileal infusion of…

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

Summary

ID

NL-OMON40999

Source
ToetsingOnline

Brief title
Repetitive brake activation

Condition

- Appetite and general nutritional disorders

Synonym
obesity, satiety

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Top Institute of Food and Nutrition;Wageningen

Intervention

Keyword: Food intake, Intestinal brake, Repetitive brake, Small intestine

Outcome measures

Primary outcome

Difference in ad libitum meal intake (as measured during ad libitum pasta meal)

Secondary outcome

Difference in satiation (as measured by VAS) per time point

Measurements in plasma of the gut hormones CCK, GLP-1, PYY, insulin and glucose

Difference in gastric emptying

Difference in duodenocaecal transit time

Difference in galbladder volume

Study description

Background summary

The appearance of intact macronutrients in the small intestine induces an intestinal brake; a negative feedback mechanism from different parts of the intestine to the stomach, the small intestine and to the central nervous system. These processes inhibit food processing, appetite sensations and food intake, and furthermore they increase feelings of satiety and satiation. Several studies showed that intraileal infusion of nutrients resulted in a reduction in food intake. However only acute effects were investigated in these studies and thus far it is not know whether repetitive (intermittent) infusion results in adaptation to repeated exposure and, thus, a lowered ileal brake response.

Therefore the current study aims to investigate the effect of repetitive ileal brake activation on food intake, satiety, gastrointestinal peptide release (CCK, GLP-1, PYY, glucose and insulin) and gut motility (gastric emptying, gallbladder volume and orocaecal transit time). In this study we will infuse

casein (intervention group) or tap water (placebo group) into the ileum of healthy volunteers. This will be done on 4 consecutive days (Tuesday, Wednesday, Thursday and Friday) so that we are able to elucidate the effect of repetitive ileal brake activation.

Study objective

Aim: To determine the effect of repetitive ileal brake activation on food intake, satiety, gastrointestinal peptide release (CCK, GLP-1, PYY, glucose and insulin) and gut motility

Hypothesis: We hypothesize that after repetitive ileal infusion of casein, ileal brake activation on day 4 results in a similar reduction in food intake compared to test day 1.

Primary objective: To investigate the effect of repetitive ileal infusion on ad libitum food intake

Study design

Explorative, randomized, double blind, placebo controlled study

Intervention

Infusing casein into the ileum

Study burden and risks

Blood sampling: on each test day (test day 1-4), after the positioning of the nasoileal catheter by fluoroscopy, a flexible intravenous cannula (Biovalve 1,0mm) is inserted into an antecubital vein in the fore-arm for blood sampling. Per time point 8mL of blood is drawn, totalling 72mL per test day (with a total of 288mL for the 4 test days). After collection (immediately after collection DPP-IV inhibitor will be added to the tube), K2EDTA tubes will be centrifuged at 2500 rpm for 10 min at 4°C. The supernatant will be collected and this will be centrifuged again at 4000 rpm for 10 min at 4°C. Plasma will be collected in 1-mL aliquots and stored at -80°C until analysis. During blood sampling, the volunteers will remain seated in a comfortable chair, with an adjustable back. No side effects are expected when sampling blood in this manner.

VAS scores for satiety and GI symptoms Scores for satiety feelings (e.g., satiety, fullness, hunger, prospective feeding, desire to eat, desire to snack) and gastrointestinal symptoms (burning, bloating, belching, cramps, colics, warm sensation, sensation of abdominal fullness, nausea and pain) will be measured using Visual Analogue Scales (VAS, 0 to 100 mm) anchored at the low end with the most negative or lowest intensity feelings (e.g., extremely

unpleasant, not at all), and with opposing terms at the high end (e.g., extremely pleasant, very high, extreme). Volunteers will be asked to indicate on a line which place on the scale best reflects their feeling at that moment. The scoring forms will be collected immediately so that they cannot be used as a reference for later scorings.

Catheter placing and fluoroscopy: The subjects will perceive mild discomfort during the placement of the catheter. Each test week starts with inserting a nasoileal tube. The radiation exposure during the positioning of the feeding tube is minimal (0.05 mSv). The total exposure to radiation (during all test days) will be approximately 0.20 mSv (0.05 mSv x 4) , which equals the radiation, which is received during 2 return flight from Amsterdam to Sydney in an aeroplane at a 4-km altitude (www.nrg- nl.com). Since the catheter will be in situ for 4 days and this can result in minor discomfort. Subjects can, at any time, come in contact with the investigator if any problems occur. All participants are healthy volunteers and we don't expect any health benefits or disadvantages.

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

• Based on medical history and previous examination, no gastrointestinal complaints can be defined.
• Age between 18 and 65 years. This study will include healthy adult subjects (male and female). Women must be taking oral contraceptives.
• BMI between 18 and 25 kg/m2)
• Weight stable over at least the last 6 months

Exclusion criteria

• History of severe cardiovascular, respiratory, urogenital, gastrointestinal/ hepatic, hematological/immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological/psychiatric diseases, allergy, major surgery and/or laboratory assessments which might limit participation in or completion of the study protocol. The severity of the disease (major interference with the execution of the experiment or potential influence on the study outcomes) will be decided by the principal investigator.
• Use of medication, including vitamin supplementation, except oral contraceptives, within 14 days prior to testing
• 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 180 days prior to the study
• Major abdominal surgery interfering with gastrointestinal function (uncomplicated appendectomy, cholecystectomy and hysterectomy allowed, and other surgery upon judgement of the principle investigator)
• Dieting (medically prescribed, vegetarian, diabetic, macrobiological, biological dynamic)
• Pregnancy, lactation
• Excessive alcohol consumption (>20 alcoholic consumptions per week)
• Smoking
• Blood donation within 3 months before the study period
• Self-admitted HIV-positive state
• Evidence of casein or hypersensitivity

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2014
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	23-10-2014
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	NL50301.068.14