The effect of duodenal, ileal or combined infusion of tastants on food intake

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To investigate the effect of intraduodenal, intraileal and combined infusion of a combination of tastants versus infusion of placebo on food intake.

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

Summary

ID

NL-OMON45433

Source
ToetsingOnline

Brief title
The effect of tastants on food intake

Condition

- Appetite and general nutritional disorders

Synonym
Obesity, overweight

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Duodenal, Food intake, Ileal, Tastants

Outcome measures

Primary outcome

Food intake during an ad libitum pasta meal in the form of a pre made lasagna.

Secondary outcome

VAS scores for satiety and GI symptoms

Study description

Background summary

The appearance of tastants in the small intestine can result in the activation of 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. We will investigate the effects of intraduodenal and/or intraileal infusion of a combination of tastants (sweet (rebaudioside A), bitter (quinine) en umami (mononsodium glutamate)) and placebo on ad libitum food intake, satiation and gastrointestinal symptoms.

Study objective

To investigate the effect of intraduodenal, intraileal and combined infusion of a combination of tastants versus infusion of placebo on food intake.

Study design

Single-blind randomized placebo-controlled cross-over trial in healthy volunteers.

Intervention

Intraduodenal, intraileal or combined infusion of a combination of tastants (sweet (rebaudioside A), bitter (quinine) and umami (monosodium glutamate) versus infusion of placebo.

Study burden and risks

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. The catheter will remain in situ during the remainder of the study period. Fluoroscopy will be performed during placing as well as before and after each test day. 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 0.45 mSv (0.05 mSv x 9). The average annual radiation a habitant of the Netherlands receives is 2.61 mSv, which is well below that of other European countries (i.e. 5.52 mSv in Belgium) or the United States (6.2 mSv). 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).
- 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
- Weight <60kg
- Non-tasters of sweet, bitter or umami
- Evidence of MSG-hypersensitivity or Chinese restaurant syndrome

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-05-2017
Enrollment:	19
Type:	Actual

Ethics review

Approved WMO

Date:	29-03-2017
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	NL59530.068.16