The effect of quinine on food intake: oral sham feeding versus intragastric delivery

Published: 27-06-2018
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To investigate the effect of oral sham feeding of and intragastric delivery of quinine (a bitter agent) versus 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-OMON48861

Source
ToetsingOnline

Brief title
Quinine and food intake

Condition

- Appetite and general nutritional disorders

Synonym
Obesity, overweight

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Food intake, Gastric, Oral, Quinine

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.

Heart rate variability (HRV)

Study description

Background summary

The appearance of quinine (a bitter tastant) orally or in the gastro-intestinal tract can result in a negative feedback mechanism to the central nervous system. These processes inhibit food processing, appetite sensations and food intake. Furthermore, they can increase feelings of satiety and satiation. We will investigate the effects of oral sham feeding and intragastric delivery of quinine (a bitter agent) versus placebo.

Study objective

To investigate the effect of oral sham feeding of and intragastric delivery of quinine (a bitter agent) versus placebo on food intake.

Study design

Blinded randomized placebo-controlled cross-over trial in healthy volunteers.

Intervention

Oral sham feeding of and intragastric delivery of quinine (a bitter agent) versus 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, pain and

relaxation/tensness) 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.
Heart rate variability (HRV) will be measured four times per test day by placing an ECG lead on the participant.

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 from 18 until 65 years. This study will include healthy adult subjects (male and female).
- BMI from 18 until 25 kg/m2
- Bodyweight stable over at least the last 6 months (up until 5% weight change allowed)

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 that can influence study end-points (to be discussed by medical doctor and principal investigator), including vitamin supplementation, 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 and hysterectomy allowed, and other surgery upon judgement of medical doctor and principle investigator)
- Dieting (medically prescribed, vegetarian, diabetic, macrobiological, biological dynamic)
- Unwillingness to eat lasagna bolognese meal
- Pregnancy, lactation
- Excessive alcohol consumption (>20 alcoholic consumptions per week)
- Smoking
- Non-tasters of bitter

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):	17-08-2018
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO

Date:	27-06-2018
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	NL64557.068.18