Effect of oral exposure duration and gastric energy content on gastric emptying rate

Published: 24-08-2012
Last updated: 26-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37261

Source
ToetsingOnline

Brief title
Gastric emptying study

Condition

- Other condition

Synonym
obesity, overweight

Health condition

overweight and obesity

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Het is researcher initiated;maar het wordt betaald door geld dat over is van derde geldstromen.

Intervention

Keyword: Food intake regulation, Gastric emptying rate, Oral/gastric contribution, Satiety

Outcome measures

Primary outcome

The primary outcomes is: differences in gastric emptying rates.

Gastric emptying will be measured with a non-invasive breath test. Subjects will come to the study centre and will receive the gastric load which is labelled with a stable isotope: i.e. 13C. Breath samples will be collected at ten different moments: 2 before the treatment and 8 times after the treatment. In the breath samples the concentration of 13C (as part of 13CO2) will be determined as a measure for gastric emptying. The collected breath samples will be analysed for 13-C isotopic enrichment of the expired CO2 using Isotope Ratio Mass Spectrometry. The differences between the treatments in recovery of the isotope will be the outcome measures for gastric emptying.

Secondary outcome

The secondary outcome is:

Subjective feelings of satiety: To measure subjective feelings of satiety, subjects will be asked multiple times to rate their feelings of satiety on a questionnaire. This *Appetite questionnaire* will consist of seven dimensions, i.e. hunger, fullness, prospective consumption, desire to eat, desire to eat something sweet, desire to eat something savoury, and thirst. The rating will

be done by means of a Visual Analogue Scale (VAS), where subjects have to mark a spot on a 100 mm horizontal line. This will be done at nine different moments during each test session. Lines will be anchored by *not at all ** on the left side and *extremely ** on the right side.

Study description

Background summary

One of the major issues in the current food-rich environment is that many popular foods promote a positive energy balance, because of their low satiating efficiency per calorie. One of the reasons for this may be the quick passage through the mouth. In our last two studies (ABR: NL30728.081.09 and NL35319.081.11), subjects simultaneously received oral and gastric stimulation, which were manipulated independently of each other. In the last study (NL35319.081.11) the volume of the gastric load was kept the same, but the energy content was varied. We found that appetite feelings were both affected by long oral exposure duration and high energy density of the gastric load. However, subsequent energy intake was mainly affected by energy density of the gastric load. We expect that the rate of gastric emptying might clarify these differences in outcome between appetite ratings and energy intake. Therefore we want to investigate the gastric emptying rate.

Study objective

The primary objective of this study is to investigate the effect of - short vs. long - oro-sensory exposure combined with a gastric load - low vs. high in energy -, on gastric emptying rate.
As secondary outcome we want to investigate the effect of - short vs. long - oro-sensory exposure combined with a gastric load - low vs. high in energy -, on subjective feelings of satiety.

Study design

This is a randomized, cross over, single centre, trial with 5 treatments and a wash out period of at least 5 days in between test sessions. Subjects will have a naso-gastric tube inserted in all 5 treatments.

Intervention

Treatments vary in oral exposure duration (0, 1 or 8 min) and in energy content

of the gastric load (0, 100 or 700 kcal) in 500 ml. There are 5 different treatments:
A: 1min oral exposure with 100kcal/500ml gastric load,
B: 8 min oral exposure with 100kcal./500ml gastric load,
C: 1 min oral exposure with 700kcal/500ml gastric load,
D: 8min oral exposure with 700kcal/500ml gastric load,
E: control treatment: no oral exposure with 0 kcal/500 ml gastric load,

Study burden and risks

The study is non-therapeutic to the participant. In healthy subjects tube insertion by an experienced nurse, is in general not a risky procedure. Subjects enrolled in the study have to visit the research centre 7 times: once for a screening, once for a training session and 5 times for the intervention. An appropriate wash-out period of at 5 days, and a training session where subjects undergo all required procedures before further inclusion, will reduce the risks and dropout rate as much as possible. In our previous study approximately 9% of the subjects (4 out the 46) stopped/were withdrawn after the training session because the tube insertion was too great a burden for them (no persistent complaints). The subjects who continued participation did not experience (medical) problems related to the tube insertion and did not withdraw because of the tube insertion. The other procedures and measurements in this study are not invasive (questionnaires, breath samples).

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

Gender: male
Age: 18 - 40 y
BMI: 18.5 - 25.0 kg/m2
Healthy: as judged by the participant

Exclusion criteria

• Smoking or drug abuse
• Gastro-intestinal diseases
• Diabetes, thyroid diseases or any other endocrine disorders
• Lack of appetite for any reason
• Hypersensitivity or food allergy for products used in this study
• Currently participating in another clinical trial or planning to start participation during this study.
• Taking any medication, except for light pain relieving medications which are available over the counter (acetylsalicylic acid or paracetamol).
• Problems with the respiratory tract, such as hyperventilation, asthma or bronchitis, which can cause problems when the naso-gastric tube is inserted.
• Working at, or doing an MSc. thesis at the Division of Human Nutrition

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-09-2012
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2012
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL40863.081.12