Oral and gastric contributions to satiety II: Effects of energy content.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26697

Source
Nationaal Trial Register

Brief title
MoMa Studie

Health condition

eating behaviour

Sponsors and support

Primary sponsor: Wageningen University, Division of Human Nutrition
Source(s) of monetary or material Support: Nestlé Research Centre

Intervention

Outcome measures

Primary outcome

Ad libitum energy intake of an ad libitum test meal served 30 minutes after start of the treatment.

Secondary outcome

To determine the effect of short/long oro-sensory exposure combined with a gastric load low/high in energy, on:

1. Subjective feelings of satiety;

2. Gastric emptying rate;

3. Furthermore we want to reproduce the results of one treatment (1min/800ml) of our previous study, to investigate the gastric emptying rate in this condition.

Study description

Background summary

Rationale:

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 previous study we found that oral exposure duration affected satiety more than volume of the gastric load. The gastric loads in the previous study differed in volume but were isocaloric (100kcal). Using gastric loads with different energy contents may give different results.

Primary objective:

The primary objective of this study is to determine the effect of - short vs. long- oro-sensory exposure combined with a gastric load - low vs. high in energy -, on subsequent energy intake.

Secondary objectives:

As secondary objectives 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 and gastric emptying rate. Furthermore we want to reproduce the results of one treatment of our previous study, to see whether quick gastric emptying rate occurs.

Design:

This is a randomized, cross over, single center, trial with 6 treatments:

1. Control: No oral exposure and no gastric load;

2. 1min oral exposure with 100kcal/500ml gastric load;

3. 8 min oral exposure with 100kcal./500ml gastric load;

4. 1 min oral exposure with 700kcal/500ml gastric load;

5. 8min oral exposure with 700kcal/500ml gastric load;

6. 1min oral exposure with 100kcal/800ml gastric load.

Subjects will have a naso-gastric tube inserted in all 6 treatments.

Number of subjects:

Forty subjects will be enrolled. With a drop-out rate of ca. 10% we will end up with 35 subjects.

Study population:

Healthy males, aged 18-40 yr, BMI 18.5-25 kg/m2, stable body weight, and who tolerate the treatments.

Study outcomes:

Ad libitum energy intake, subjective feelings of satiety and gastric emptying rate.

Study objective

Oral exposure time and energy content of the gastric load both effect subjective feelings of satiety, gastric emptying rate and subsequent food intake. A longer oral exposure time and a high gastric energy content would both increase subjective feelings of satiety and lower subsequent food intake. In addition it is expected that a high energy content of the gastric load delays the rate of gastric emptying.

Study design

Every subject will visit the laboratory 8 times:

1. For an information and screening meeting;

2. For a training session (where all study procedures are practised;

3. 6 testsessions with in each session:

A. Ad libitum lunch intake 30 min. after the treatment;

B. VAS questionnaire: Directly before, and 9, 15, 30 and 60 minutes after start the treatment;

C. Breath sample collection: 2 times before start of the treatment, and 10, 15, 20, 25 and 30 minutes after start of the treatment.

Intervention

Oral and gastric stimulation:

Subjects receive (after inclusion, IC and training session) 6 treatments. 4 treatments with 2x2 design with:

1. Oral stimulation: 1 min (low) or 8min (high) modified sham feeding;

2. Gastric stimulation: Infusion of 500ml of liquid with 100kcal or 700kcal into the stomach with a naso-gastric tube.

Besides these 4 treatments there is a control treatment: A naso-gastric tube is inserted, but there is no oral or gastric stimulation.

Furthermore we want to reproduce the results of one treatment (1min/800ml) of our previous study (NTR2173), to investigate the gastric emptying rate.

Contacts

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Eligibility criteria

Inclusion criteria

1. Gender: Male;

2. Age: ≥ 18 years and ≤ 40 years;

3. Stable body weight (change of < 5 kg body weight in the last 2 months);

4. Good physical and mental health as judged by the participant himself;

5. BMI: ≥ 18.5 and < 25 kg/m2;

6. Having signed the informed consent forms.

Exclusion criteria

1. Smoking or drug use;

2. Gastro-intestinal diseases;

3. Diabetes, thyroid diseases or any other endocrine disorders;

4. Lack of appetite for any reason;

5. Restraint eating DEBQ score ≥ 2.26 (above average);

6. Hypersensitivity or food allergy for products used in this study;

7. Currently participating or having participated in a clinical trial during the last 3 months prior to the beginning of this study;

8. Taking any medication, except for light pain relieving medications which are available over the counter (aspirin or paracetamol);

9. Problems with the respiratory tract, such as hyperventilation, asthma or bronchitis, which can cause problems when the naso-gastric tube is inserted;

10. Working at, or doing an MSc. thesis at the Division of Human Nutrition.

Information about the exclusion criteria above is requested from the subjects via an inclusion/screening questionnaire. This information is checked at the first visit of the subject.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2011
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	25-02-2011
Application type:	First submission

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
NTR-new	NL2651
NTR-old	NTR2779
Other	MEC Wageningen / ABR : 11/05 / NL35319.081.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A