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

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Oral exposure time and energy content of the gastric load both affect subjective feelings of satiety and gastric emptying rate. It is expected that a longer oral exposure time and a higher gastric energy content would both increase subjective...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22787

Bron
Nationaal Trial Register

Aandoening

eating behaviour

Ondersteuning

Primaire sponsor: Wageningen University, Division of Human Nutrition
Overige ondersteuning: Wageningen University, Division of Human Nutrition

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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. How the mouth and the stomach influence each other with regards to gastric emptying is not fully understood.

Objective of the study:

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.

Number of subjects:

Twenty-seven men will be enrolled. With an expected drop-out rate of approximately 10% we will end up with 24 subjects.

Study population:

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

Study outcomes:

Rate of gastric emptying and subjective feelings of satiety.

Doel van het onderzoek

Oral exposure time and energy content of the gastric load both affect subjective feelings of satiety and gastric emptying rate. It is expected that a longer oral exposure time and a higher gastric energy content would both increase subjective feelings of satiety and that a high energy content of the gastric load would delay the rate of gastric emptying.

Onderzoeksopzet

Every subject will visit the laboratory 7 times:

1. For an information and screening meeting;

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

3. 5 testsessions with in each session:

A. VAS questionnaire: Directly before, and and 8, 15, 22, 30, 45, 60, 75 and 90 minutes after start of the treatment;

B. Breath sample collection: 2 times before start of the treatment, and 8, 15, 22, 30, 45, 60, 75 and 90 minutes after start of the treatment.

Onderzoeksproduct en/of interventie

Oral and gastric stimulation:

Subjects receive (after inclusion, IC and training session) 5 treatments. 4 treatments with 2x2 design with:

1. Oral stimulation: 1 min or 8min 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 condition: No oral stimulation but subjects are infused with a 500ml 0kcal (noncaloric) liquid.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Gender: male;

2. Age: 18 - 40 y;

3. BMI: 18.5 - 25.0 kg/m2;

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

5. Healthy: as judged by the participant;

6. Having signed the informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Smoking or drug abuse;

2. Gastro-intestinal diseases;

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

4. Lack of appetite for any reason;

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

6. Currently participating in another clinical trial or planning to start participation during this study;

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

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

9. Working at, or doing an MSc. thesis at the Division of Human Nutrition of Wageninen University.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	17-09-2012
Aantal proefpersonen:	27
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	31-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3450
NTR-old	NTR3601
Ander register	MEC Wageningen /ABRnr. : 12/16 / NL40863.81.12;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A