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

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

Summary

ID

NL-OMON36467

Source
ToetsingOnline

Brief title
MoMa Study

Condition

- Other condition

Synonym
obesity, overweight

Health condition

overweight and obesity

Research involving
Human

Sponsors and support

Primary sponsor: Nestec
Source(s) of monetary or material Support: Nestec

Intervention

Keyword: Ad libitum intake, Food intake regulation, Oral/gastric contribution, Satiety

Outcome measures

Primary outcome

The primary outcome is ad libitum energy intake of an ad libitum test meal served 30 minutes after start of the oral exposure/ intragastric infusion. To measure energy intake, the amount of provided food will be determined, as well as the leftovers. Chemical analyses will be performed to determine the exact energy and macronutrient content of the lunch.

Secondary outcome

Secondary outcomes measures are

- subjective feelings of satiety that are measured via Visual Analogue Scale ratings. Hunger, fullness, prospective consumption, desire to eat, desire to eat something sweet, desire to eat something savoury, thirst, wellbeing and nauseous feelings will be rated.

- gastric emptying rate will be measured with a non-invasive breath test. The gastric load which the subjects receive for the gastric stimulation will be labeled with a stable isotope: 13-C acetate. After some time part of the 13-C acetate will be present in the breath of the subjects. During a test day, 7 breath samples will be collected of a subject. The rate of gastric emptying

will be determined by measuring the 13-C isotopic enrichmen in the collected

breath samples.

Gastric emptying rate of 1min/800ml treatment

The gastric emptying rate of the 1min/800ml treatment will be compared to the

control, to see whether it is significantly quicker. That might be the reason

that we did not found a significant effect of gastric filling volume on ad

libitum energy intake in our previous study.

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 the consumption of these foods leads to a relatively low satiety feeling relative to their energy content.
One of the reasons for this may be their swift passage through the mouth, which decreases sensory signalling. This decreased sensory signalling may lead to diminished CPRs and lower sensory satiety. Consumption of fast foods, like caloric liquids and highly energy-dense foods may disrupt the learned connection between sensory signals and their physiological consequences and thereby CPRs.
In order to prevent a positive energy balance upon consumption of energy dense food products, there is a need to know how sensory and gastric signals and their interaction affect satiety. The understanding of which food properties have an impact on the oral and gastric contributions to satiety creates opportunities to optimize food products in such a way that satiety is maximized.

Study objective

The primary objective of this study is to determine the effect of the duration

of oro-sensory exposure and/or energy content of the gastric load, on subsequent energy intake.

The secondary objectives of the research project are to determine the effect of short/long oro-sensory exposure combined with a gastric load low/high in energy, on:
• subjective feelings of satiety
• gastric emptying rate

Furthermore we want to reproduce the results of one treatment (1min/800ml) of our previous study (ABR nr 30728), to investigate whether the gastric load is quickly emptied.

Study design

This is a randomized, cross over, single center, trial with 6 treatments:
Control: no oral exposure and no gastric load.
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: 1min oral exposure with 100kcal/800ml gastric load,
Subjects will have a naso-gastric tube inserted in all 6 treatments.

Intervention

All subjects will receive all 6 treatments, which are described under 'study design, in randomised order. Oral stimulation is done with modified sham feeding (MSF) with cake, and gastric stimulation is done with a mixture of cake and water.

30 minutes after the start of the treatment, subjects will receive a lunch meal, and are told to eat until they are comfortably full. Ad libitum food intake during this lunch is the primary outcome of the study

Subjects will receive one treatment per test day, and between the test days a minimum of 5 testfree days will be scheduled.

Study burden and risks

Subjects will have 1 visit at the university and 7 visits at the hospital, that will last for 14.5 hours all together.

The stable isotope 13-C acetate is a natural stable isotope, it makes up about 1% of all natural carbon on earth and it is present in for example corn. Naso-gastric intubation by an experienced nurse is usually a procedure with a

low risk. Especially in healthy subjects this will not cause problems in most of the cases. We do not expect that repeated intubation - with a wash-out period of at least 5 days - will give a higher risk than a single intubation.
In our previous study (ABR nr 30728) no complications occurred, nor did any of the subjects reported enduring soreness/irritation of the nose or throat.

More insight in the sensory and gastric signals and their interaction in satiety will be present after conducting the study.
The understanding of which food properties have an impact on the oral and gastric contributions to satiety creates
opportunities to optimize food products in such a way that satiety is maximized.

Contacts

Public
Nestec

Avenue Nestle 55
CH-1800 Vervey
CH
Scientific
Nestec

Avenue Nestle 55
CH-1800 Vervey
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male, healthy (based on subjects own judgement), aged between 18 and 40 years, BMI between 18.5 and 25 kg/m2, stable body weight (no changes larger than 5kg over the past 2 months)

Exclusion criteria

• Smoking or drug use
• Taking any medication, except for light pain relieving medications which are available over the counter (aspirin or paracetamol).
• Gastro-intestinal diseases
• Diabetes, thyroid diseases or any other endocrine disorders
• Problems with the respiratory tract, such as hyperventilation, asthma or bronchitis, which can cause problems when the naso-gastric tube is inserted.
• Lack of appetite for any reason
• Restraint eating DEBQ score >= 2.26 (above average)
• Hypersensitivity or food allergy for products used in this study
• Currently participating or having participated in a clinical trial during the last 3 months prior to the beginning of this study.
• 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):	20-04-2011

Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2011
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	NL35319.081.11