

The effect of viscosity on the rate of gastric emptying

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To investigate whether the rate of gastric emptying differs between a low viscosity milk product and an iso-caloric high viscosity milk product.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON34934

Source

ToetsingOnline

Brief title

Gastric emptying and viscosity

Condition

- Appetite and general nutritional disorders

Synonym

obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: Top Institute Food and Nutrition

Intervention

Keyword: breath test, food intake, gastric emptying, viscosity

Outcome measures

Primary outcome

The main study outcome is gastric emptying (and the variation in that measurement). Gastric emptying will be measured with a non-invasive breath test. The subject will come in fasting state to the research centre and ingest the test product which is labelled with ^{13}C . The test foods consist of 2 chocolate flavoured milk products, differing in viscosity. Breath samples will be collected before consumption of the food and at 15 minute intervals during 3 hours. Breath samples will be analyzed on concentration of ^{13}C . ^{13}C recovery ($T_{1/2}$ and T_{lag}) will be used as a measure for gastric emptying.

Secondary outcome

Appetite and wellbeing ratings will be measured during the test by means of Visual Analogue Scales.

Study description

Background summary

We have shown previously that low viscosity products seem to elicit weak satiating responses compared to high viscosity products. About 30% more low viscosity milk products are consumed to satiation compared to iso-caloric high viscosity products. As high viscous products are also known to be released much slower from the stomach, it might be that the difference in satiating capacity can be explained by differences in gastric emptying.

Study objective

To investigate whether the rate of gastric emptying differs between a low viscosity milk product and an iso-caloric high viscosity milk product.

Study design

Cross-over experiment with 2 gastric emptying measurements per subject. In one of the conditions a fixed amount of 500g of the low viscosity product will be consumed, in the other condition a fixed amount of 500g of the high viscosity product. Food products are randomized and balanced.

Intervention

Cross-over experiment with 2 gastric emptying measurements per subject. In one of the conditions a fixed amount of 500g of the low viscosity product will be consumed, in the other condition a fixed amount of 500g of the high viscosity product. Food products are randomized and balanced.

Study burden and risks

Subjects will have to come 2 times to the research centre to undergo the breath test (3-4 hours). Prior to participation subjects will have a screening visit of ca. 15 minutes (inclusion questionnaire; measurement of weight and height; explanation of the procedure).

The study is non-therapeutic to the participant. The risk associated with participation is negligible. Compared to other studies, the burden can be considered as low. No invasive measurements are present.

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

*Apparently healthy, self reported

*Young adult males: 18-30 year

*Normal weight: BMI 18.5-25 kg/m²

*Used to eating breakfast (> 5 times per week)

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Exclusion criteria

*Loss of appetite

*Weight change of >5kg during the last 2 months

*Being on a weight loss diet

*On a prescribed diet that interferes with the study foods

*Bowel or stomach disorder

*Diabetes or thyroid disorder

*Food intolerance or allergy for foods that are provided during the study

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO	
Date:	10-03-2010
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	NL31352.081.10