gastric emptying properties of a whisked drink

Published: 09-11-2011
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To test the gastric emptying properties of a whisked drink.

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

Summary

ID

NL-OMON35690

Source
ToetsingOnline

Brief title
Gastric emptying study

Condition

- Other condition

Synonym
gastric emptying

Health condition

maaglediging

Research involving
Human

Sponsors and support

Primary sponsor: Unilever
Source(s) of monetary or material Support: Unilever Research & Development Vlaardingen BV financiert het hele onderzoek.

Intervention

Keyword: Gatric emptying, Nutrition

Outcome measures

Primary outcome

Gastric emptying time, measured by means of the PK curve of a biomarker.

Secondary outcome

PK profile of the biomarker

Study description

Background summary

Gatric emptying time plays a rol in the uptake of certain substances. The food that is tested in this study may affect the gastric emptying time.

Study objective

To test the gastric emptying properties of a whisked drink.

Study design

Placebo controlled, randomized, cross-over study with 2 treatments (test product and placebo). The gastric emptying properties of the test product vs. placebo will be tested by means of a marker in the blood.

Intervention

A whisked drink drink vs. placebo (corrected for energy intake).

Study burden and risks

1 screening:
- BMI
- Questionnaire
- Informed Consent

2 visit days of approximately 10,5 hours

- Placing a canula
- 14 blood withdrawals
- diet restrictions (arriving fasted at visit days, standardized meals and drinks on visit days)
- 10 blood withdrawal via finger prick (applicable to only half of the study population)

Risk: 2 times placing a canula for blood withdrawal.

Contacts

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Unilever

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Men
Age 18-45 yrs

BMI 20-30 kg/m2

Exclusion criteria

Unilever employee
Smokers
Dislike to intolerance to the test products

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-11-2011
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	09-11-2011
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	NL38068.081.11