Gastric emptying of plant sterol-containing mini drinks in different meal intake scenarios and their effect on gallbladder emptying

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The aim of this study is to gain insight in the mechanisms that may be involved in the effects of plant sterol drinks on gastric emptying and gallbladder motility. In order to test this, we compare the different effects of the consumption of a plant...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON35720

Source
ToetsingOnline

Brief title
Plant sterol study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
gallbladder motility, gastric emptying

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Unilever,Unilever bv

Intervention

Keyword: Cholecystokinin, Gall bladder volume, Gastric emptying, Plant sterol

Outcome measures

Primary outcome

Primary study parameters are gastric emptying and gallbladder volume.

Secondary outcome

Secondary study parameters are plasma CCK, plant sterol concentrations.

Study description

Background summary

Plant sterols can play an important role in lowering plasma cholesterol. The extent to which plant sterols can reduce plasma cholesterol levels depends on the intake scenario. We suggest that the difference in these effects depends on gastric emptying and bile secretion.

Study objective

The aim of this study is to gain insight in the mechanisms that may be involved in the effects of plant sterol drinks on gastric emptying and gallbladder motility. In order to test this, we compare the different effects of the consumption of a plant sterol containing drink prior to, during and after a standardized meal.

Study design

We will implement a randomized controlled cross-over design.

Intervention

Consumption of plant sterol containing drinks and test meals.

Study burden and risks

All products that will be used for the study, are harmless. Both, the plant sterol containing drink as well as the standardized meal that will be used in this study, are commercially available. Paracetamol and 13C octanoic acid are pharmaceutically tested and are safe.
Echoscopy and breath sample donnation are both without any risk for the volunteer. Insertion of the cannula may cause a bruise or swelling afterwards. Further complications that may be involved with blood sampling are a perceived sense of dizziness or fainting, due to blood exposure.

Contacts

Public
Universiteit Maastricht

P.O. Box 616
6200 MD
NL
Scientific
Universiteit Maastricht

P.O. Box 616
6200 MD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Signed informed consent form
• Sex: male

• Age: 18-55 years
• Body Mass Index (BMI): 20-30 kg/m2

Exclusion criteria

• History of severe cardiovascular, respiratory, urogenital, gastrointestinal/ hepatic, hematological/immunologic, HEENT (head, ears, eyes, nose, throat), dermatological/connective tissue, musculoskeletal, metabolic/nutritional, endocrine, neurological/psychiatric diseases, allergy, major surgery which might limit participation in or completion of the study protocol.
• Use of any medication on regular basis.
• Use of paracetamol prior to treatment (<= 48 hour).
• Use of plant sterol/stanol enriched products or supplements.
• Blood donations less than three months previous to study enrolment.
• Known hypersensitivity or allergy towards paracetamol.
• Hyperlipidaedimia (TG > 3 mmol/L and/or tot. chol. > 8 mmol/L)
• Corn products prior to treatment (<= 48 hour)
• Presence of gallbladder stones

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2010
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	17-09-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	08-03-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT00940849
CCMO	NL27585.068.09