The effect of orally applied encapsulated lipids in yoghurt on satiety and food intake: a randomized single-blind study with cross-over design

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To explore the ability of encapsulation of orally applied lipids in a yoghurt snack to modify ad libitum food intake and satiety, without GI symptoms.

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

Summary

ID

NL-OMON43311

Source
ToetsingOnline

Brief title
Lipid encapsulation for ileal brake activation

Condition

- Appetite and general nutritional disorders

Synonym
obesity, overweight

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: encapsulation, ileal brake, safflower oil, slow release

Outcome measures

Primary outcome

To investigate whether encapsulation of lipids decreases ad libitum food intake compared to non-encapsulated lipids in a formulation with equal nutrients (control).

Secondary outcome

- Feelings of satiety (VAS scores)

- Occurance and severity of GI symptoms (VAS scores)

- Yoghurt type specific differences in food intake, satiety and adverse GI symptoms

Study description

Background summary

Sensing of lipid fractions in the small intestine can induce negative feedback mechanisms from different parts of the intestine to the proximal gastrointestinal (GI) tract including stomach, gallbladder and pancreas but also to the central nervous system. This negative feedback process is able to inhibit food digestion, appetite sensations and food intake, and is able to increase feelings of satiety and satiation. The ileal brake is considered a potent feedback mechanism not only during short-term intervention with ileal lipid infusion, but also as powerful long-term weight management strategy with orally ingested ileal lipid deliveryhen ingested orally. However, the major part of dietary lipids will be digested and absorbed in the proximal small intestine and is not likely to reach the distal ileum and induce the strong ileal brake feed back mechanism. To prevent orally applied lipids to be proximal digested and absorbed, we designed a food-grade encapsulation system that releases free fatty acids from safflower oil in the more distal small intestine. The current study will be an explorative study to proof the concept of ileal brake activation: the encapsulated lipid will be added to and mixed

with yoghurt (A), and the subsequent satiety and food intake will be compared to an equicaloric mixture of non-encapsulated nutrients (control, yoghurt B) with the same amount of lipids, and the encapsulation components.

Study objective

To explore the ability of encapsulation of orally applied lipids in a yoghurt snack to modify ad libitum food intake and satiety, without GI symptoms.

Study design

Randomized, single-blind, placebo-controlled intervention study with cross-over design.

Intervention

Every subject receives two treatments on two different days with at least one week in between, following a randomized cross-over design. On the test day, the subjects will arrive in fasted state and receive a standardized breakfast (small, low in fat, t=0 min). Once major part of the breakfast has been emptied from the stomach (t=90 min), they receive a yoghurt (0.2 L) that contains emulsified safflower oil (6 g) either encapsulated (yoghurt A) or non-encapsulated (control, yoghurt B; same oil droplet size as intervention and in presence of *empty* encapsulation matrix). Two hours after the intervention yoghurt, once the lipid will be released to the distal small intestine, ad libitum meal intake will be measured (t=210 min).

Study burden and risks

The subjects (in total 35) will have to visit Maastricht University on three occasions: once to fulfil the screening and get an instruction (about half an one hour) and two times to attend the test days (about four hours per test day). The test days will be non-invasive: consumption of a breakfast, yoghurt snack, and lunch; and in between filling questionnaires on satiety feelings (satiety, fullness, hunger, desire to eat, desire to snack) and GI symptoms (bloating, discomfort, pain, nausea). These attributes will be measured using Visual Analogue Scales (VAS, 0 to 100 mm) scores, with the most negative or lowest intensity feelings at the low end and the opposing terms at the high end. The subject will be asked to indicate his feeling at that moment.
*

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

BMI (25-30), healthy (Based on medical history and previous examination, no serious gastrointestinal complaints can be defined)

Exclusion criteria

milk allergy/intollerance, dieting, pregnancy/lactation, excessive alcohol consumption, intention to stop smoking, severe disease, major abdominal surgery, abnormal eating behaviour

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	35
Type:	Actual

Ethics review

Approved WMO

Date:	21-12-2016
Application type:	First submission
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
Other	nader te bepalen
CCMO	NL59245.068.16