The effect of repetitive intake of lipids in alginate gel on food intake and satiety

Published: 08-05-2019
Last updated: 09-04-2024

Primary Objective: To investigate the effect of repetitive intake of lipids in alginate gel over 4 days on ad libitum food intake in overweight subjectsSecondary Objective(s):- To investigate the effect of repetitive intake of lipids in alginate gel...

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

Summary

ID

NL-OMON55429

Source
ToetsingOnline

Brief title
Repetitive lipid intake and food intake

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: food intake, lipids in alginate gel, satiety

Outcome measures

Primary outcome

The main study parameter is the intake of ad libitum meal (kcal), as measured during lunch (based on cumulated weight reduction of the food items provided) and during a pasta dinner (also based on weight reduction of the plate assuming a homogenous meal) on the fourth day of consumption of the test product.

Secondary outcome

Acute effect on ad libitum food intake, acute vs repetitive on ad libitum food intake, food intake in normal living setting, feelings of satiety (VAS scores) and energy intake compensation.

Study description

Background summary

Direct infusion of lipids into different parts of the human small intestine has demonstrated to decrease food intake and subjective appetite feelings, to increase production of the satiety hormones GLP-1, PYY, and CCK, and diminishes gastrointestinal (GI) motility. Amongst oils with different degree of fatty acid saturation, safflower oil (high in linoleic acid, C18:2) was found the strongest inducer of the ileal brake. When ingested orally, however, the major part of dietary lipids will be digested and absorbed in the proximal small intestine and are not likely to induce the ileal brake mechanism. Incorporating small lipid droplets into millimeter-sized calcium (Ca)-alginate gel particles has shown promising results for ileal brake activation. Oral intake of these lipid containing gels have proven to reduce food intake in humans without inducing gastrointestinal symptoms. Contrastingly, to date little is known about repetitive activation of mechanisms of satiety and the effect on food intake. It is not known whether repetitive ileal brake activation provides a stronger brake or whether this will lead to a blunted response and adaptation. Therefore, in the present study we will investigate the effect of repetitive

intake of safflower oil droplets in Ca-alginate gels in yogurt over four days on ad libitum food intake, satiety feelings and energy intake compensation.

Study objective

Primary Objective: To investigate the effect of repetitive intake of lipids in alginate gel over 4 days on ad libitum food intake in overweight subjects
Secondary Objective(s):
- To investigate the effect of repetitive intake of lipids in alginate gel over 4 days on energy intake compensation, satiety feelings and GI symptoms in overweight subjects
- To investigate the acute effect of intake of lipids in alginate gel over 1 day on ad libitum food intake, energy intake compensation, satiety feelings and GI symptoms in overweight subjects
- To compare the effect between the intake of lipids in alginate gel on the first day and, after a 4 days treatment period, on the fourth day on ad libitum food intake, energy intake compensation, satiety feelings and GI symptoms in overweight subjects
- To investigate the effect of intake of lipids in alginate gel on food intake in normal living setting

Study design

Single-blind, randomized, controlled trial with two treatments in a cross-over design.

Intervention

Each subject will receive two treatments in two research periods separated with a minimum of one-week wash-out, and a maximum of 6 weeks in between research periods. Each subject will consume the test product during four consecutive days and participate in a test day on the first and last day of each research period.

Study burden and risks

The subjects (in total 44) will have to visit the Centre for Healthy Eating and Food Innovation (HEFI) at Maastricht University Campus Venlo (Sint Jansweg 20, Villa Flora building, 5928RC, Venlo), on five occasions: once to sign the informed consent form, fulfil the screening and get a verbal explanation (about 30-60 minutes) and four times to attend the test days (about 9 hours per test day). The test days will be non-invasive: consumption of a breakfast, yogurt snack, lunch, smoothie snack, and dinner; 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 VAS (0 to 100 mm), with the most negative or lowest intensity

feelings at the low end and the opposing terms at the high end. Finally, the subjects will be asked to complete a food diary on six occasions corresponding to the 2 days before starting each research period, and the 4 days where the subjects will consume the test products in a normal living setting in each research period.

Contacts

Public
Universiteit Maastricht

Nassaustraat 36
Venlo 5911BV
NL
Scientific
Universiteit Maastricht

Nassaustraat 36
Venlo 5911BV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age is between 18 and 65 years;
BMI between 25-30 kg/m2;
Less than 5% weight change over the last 6 months.

Exclusion criteria

Following a diet;
Drink more than 20 alcoholic drinks per week;
Allergic/intolerant to milk;
Smoker

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-10-2019
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	08-05-2019
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
ClinicalTrials.gov	NCT03901157
CCMO	NL66473.068.19