Effect of droplet size of a fat emulsion, when given directly into the small intestinell intestinal on satiety and food intake in healthy volunteers.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26271

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Obesity
Overgewicht, obesitas

Sponsors and support

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

Health Institute

Intervention

Outcome measures

Primary outcome

To assess whether the fat droplet size in an emulsion affects satiety (as measured by visual analogue scales) and food intake (during ad libitum lunch) when infused into the duodenum and when infused into the ileum.

Secondary outcome

To assess whether the fat droplet size in an emulsion affects gastric emptying, intestinal transit time and secretion of peptides known to affect satiety (CCK, PYY) when infused into the duodenum and when infused into the ileum.

Study description

Study objective

Long-chain triglyceride (LCT) emulsions with very small droplet sizes (fine emulsion) will lead to enhanced postprandial satiety and reduced energy intake in a subsequent meal, as compared to LCT emulsions with relatively large droplet sizes (coarse emulsion). Infusion in the ileum will enlarge this effect as compared to the duodenum.

Study design

t=0
t=30
t=45
t=60
t=75
t=90
t=105
t=120
t=135
t=150
t=165
t=180
t=195
t=210

t=240

Intervention

6 g of fine (droplet size 1 micron) or coarse (droplet size 15 micron) oil emulsion will be administered to the duodenum or the ileum.

Contacts

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Eligibility criteria

Inclusion criteria

1. Signed informed consent form

2. Sex: male or female

3. Age: 18-55 years

4. Body Mass Index (BMI): 18-32 kg/m2

Exclusion criteria

1. Evidence 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 and/or laboratory assessments which might limit participation in or completion of the study protocol

2. Gastrointestinal or hepatic disorders influencing gastrointestinal absorption or transit

3. The use of psychotropic drugs, including: benzodiazepines or alcohol in excess of 21 units/week for males and 14 units/week for females

4. Concomitant medication that can increase gastric pH (e.g. antacids, protonpump-inhibitors, prostaglandins, anticholinergic agents, H2-receptor antagonists), or alter gastric emptying (e.g. metoclopramide, cisapride, domperidone and erythromycin, anticholinergics, tricyclic antidepresants, narcotic analgetics, adrenergic agents, calcium channel blockers), or alter intestinal transit (e.g. loperamide, chemical/osmotic/bulk laxatives) ,or influence satiety/energy intake (e.g. sibutramine, glucocorticoids, anabolic steroids)

5. Intolerance of Slim Fast product or of ingredients of the ad libitum meal

6. Pregnancy, lactation, wish to become pregnant during study, or having a positive pregnancy test at inclusion

7. Reported unexplained weight loss/gain of more than 2 kg in the month before the study enrollment

8. Eating disorders detected using the “SCOFF” questionnaire (in Dutch translation), and high or very high-restrained eaters as measured by the Dutch Eating Behavior Questionnaire (25;26) – see Appendix 1 and 2.

9. Blood donations less than three months previous to study enrollment

10. One or more of the following dietary habits: medically prescribed diets, weight reduction diets, or vegetarian/macrobiotic/biologically dynamic food habits

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-04-2005
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	31-10-2008
Application type:	First submission

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
NTR-new	NL1454
NTR-old	NTR1515
Other	P04.224 : 04C9
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A