The effect of intraileal infusion of fat emulsions, differing in degree of saturation, on satiety and food intake after a liquid meal replacement.

No registrations found.

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

Summary

ID

NL-OMON23841

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Obesity.

Sponsors and support

Primary sponsor: LUMC - Dept of Gastroenterology - Hepatology
PO box 9600
2300 RC Leiden
fax nr.:0715248115
tel. nr.:0715263507

Source(s) of monetary or material Support: Unilever Health Institute
Energy, Weight Control and Performance skill base
Unilever Research Vlaardingen
PO Box 114
3130 AC Vlaardingen

The Netherlands

Intervention

Outcome measures

Primary outcome

To assess whether emulsions differing in degree of saturation, have different effects when administered in the ileum, on satiety as measured by visual analogue scales, and food intake during ad libitum lunch.

Secondary outcome

To assess the effect of emulsions differing in degree of saturation, when infused in the ileum on gastric emptying, intestinal transit time and on secretion of peptides known to affect satiety.
Peptides we will measure are Ghrelin and CCK as proximal gut hormones and Apo A-IV and PYY as distal gut hormones (ileal brake).

Study description

Background summary

In a double blind placebo controlled crossover design, saline (control) or a 5 g emulsion consisting either of mainly unsaturated fats (18:0), mono-unsaturated fat (18:1) or di-unsaturated fat (18:2) will be administered to the ileum on 4 consecutive days, using a 270 cm catheter.

Study objective

Long-chain triglyceride (LCT) emulsions with di-unsaturated fatty acids will lead to enhanced postprandial satiety and reduced energy intake in a subsequent meal, as compared to LCT emulsions with mono-unsaturated or saturated fatty acids.

Study design

N/A

Intervention

Saline (control) or a 5 g emulsion consisting either of mainly unsaturated fats (18:0), mono-unsaturated fat (18:1) or di-unsaturated fat (18:2) will be administered to the ileum on 4

consecutive days, using a 270 cm catheter.

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2005
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	15-09-2005
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	NL441
NTR-old	NTR481
Other	: N/A
ISRCTN	ISRCTN51742545

Study results

Summary results

N/A