

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

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/03/2009	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR481

Study information

Scientific Title

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Double blind placebo controlled crossover design

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Quality of life

Participant information sheet

Health condition(s) or problem(s) studied

Obesity, overweight (BMI greater than or equal to 25 kg/m²)

Interventions

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.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

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 measures

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).

Overall study start date

26/09/2005

Completion date

24/12/2005

Eligibility**Key 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

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

15

Key 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 antidepressants, narcotic analgesics, 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 enrolment

Date of first enrolment

26/09/2005

Date of final enrolment

24/12/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands

2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (Netherlands)

Sponsor details

Department of Gastroenterology and Hepatology

P.O. Box 9600

Leiden

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2300 RC

Sponsor type

Hospital/treatment centre

Website

<http://www.lumc.nl/>

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Industry

Funder Name

Unilever Health Institute (Netherlands) - Unilever Research Vlaardingen

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2009		Yes	No