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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

Registration date
27/01/2006

Overall study status
Completed

Last Edited
25/03/2009

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/m^2)

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/m^2

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
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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