Influence of distribution of small intestinal delivery of fat on satiety and energy intake in healthy volunteers.

No registrations found.

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

Summary

ID

NL-OMON27589

Source
NTR

Brief title
N/A

Health condition

obesity, overweight, weight management

Sponsors and support

Primary sponsor: Division of Gastroenterology, Department of Internal Medicine, University Hospital Maastricht (AZM)
Source(s) of monetary or material Support: Unilever Research Vlaardingen, Unilever Health Institute

Intervention

Outcome measures

Primary outcome

The main study parameters are differences in satiety scores (as measured by visual analogue

scale (VAS)) per time point and as AUC and differences in food intake during an ad libitum meal.

Secondary outcome

Secondary parameters are plasma concentrations of gut peptides and difference in gastric emptying T1/2 and small bowel transit time.

Study description

Background summary

Ready-to-drink (RTD) meal replacements are effective in reducing body weight in people following an overall diet plan. However, feelings of hunger return already within two hours after ingestion of these drinks, and this may influence compliance to the diet plan.

In order to optimize the satiating potency of triacylglycerols, we previously performed a study in which we varied the location of fat infusion, showing that activation of the ileal brake by ileal fat infusion reduced food intake by an additional 12 % compared to the same emulsion infused in the duodenum, thereby demonstrating the potency of the ileal brake to reduce food intake and satiety.

In rats, another method of increasing the satiating potency of a meal is by increasing the spread of fat emulsion over the small intestinal surface.

In the present study we will test the optimal distribution of an emulsion in the small intestine infusion, in order to maximize the effect on satiety parameters and food intake during an ad libitum-lunch. Furthermore, we aim to compare whether in humans increasing the surface area of infusion leads to an increase in inhibition of hunger and food intake.

Study objective

We hypothesise that increasing the luminal surface exposed to the emulsion will lead to a decrease in hunger and food intake, but that otherwise, the ileal infusion will have the greatest impact on these parameters.

Study design

-15 min;

0 min;

30 min;

45 min;

60 min;

75 min;

90 min;

105 min;

120 min;

135 min;

150 min;

165 min;

180 min;

210 min.

Intervention

After intubation with a naso-ileal catheter, volunteers will three times receive an intra-intestinal infusion with a fat emulsion, and once a saline control.

Contacts

Public
University Hospital Maastricht (azM)
Department of Internal Medicine
Division of Gastroenterology & Hepatology
PO Box 5800
J Maljaars
Maastricht 6202 AZ
The Netherlands
+31 (43) 3882983
Scientific
University Hospital Maastricht (azM)
Department of Internal Medicine
Division of Gastroenterology & Hepatology
PO Box 5800
J Maljaars

Maastricht 6202 AZ
The Netherlands
+31 (43) 3882983

Eligibility criteria

Inclusion criteria

1. Sex: male or female;

2. Age: 18-55 years;

3. Body mass index(BMI): 18-29 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. 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;

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;

11. Reported working on late/night shifts.

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):	01-09-2007
Enrollment:	15
Type:	Actual

Ethics review

Positive opinion

Date:	11-12-2008
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	NL1514
NTR-old	NTR1584
Other	MEC 08-1-008 : 0710
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A