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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27589

Bron
NTR

Verkorte titel
N/A

Aandoening

obesity, overweight, weight management

Ondersteuning

Primaire sponsor: Division of Gastroenterology, Department of Internal Medicine, University Hospital Maastricht (AZM)
Overige ondersteuning: Unilever Research Vlaardingen, Unilever Health Institute

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

-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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Sex: male or female;

2. Age: 18-55 years;

3. Body mass index(BMI): 18-29 kg/m2.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2007
Aantal proefpersonen:	15
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-12-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1514
NTR-old	NTR1584
Ander register	MEC 08-1-008 : 0710
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A