CasWhey study: Casein protein versus Whey protein

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

Samenvatting

ID

NL-OMON28888

Bron
Nationaal Trial Register

Verkorte titel
CasWhey study

Aandoening

Amino acid absorption after gastric bypass surgery
Satiety
Secretion of anorexigenic hormones

Ondersteuning

Primaire sponsor: Medical Center Leeuwarden
Overige ondersteuning: 1. University of Groningen/Campus Fryslân
2. Medical Centre Leeuwarden
3. University Medical Centre Groningen / Department of Endocrinology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- To assess and compare the net incremental area under the curve of satiety-related plasma amino acids and derivatives in response to lactase-containing milk supplemented with either casein or whey protein in a randomized controlled cross over study in subjects 12-18 months after primary gastric bypass surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Dietary protein could be of potential great importance to improve postoperative outcomes after bariatric surgery given its effects in the non-surgical population on preservation of fat free mass, induction of satiety and prevention of protein malnutrition. And while the quantity of dietary protein is the main focus of interest in many studies, the amino acid composition of the ingested proteins may also be of importance. Our systematic review on the effect of dietary protein after gastric bypass surgery concluded there might be an essential beneficial role, but due to limited amount of literature and the diversity in main outcomes solid evidence could not be provided and more high quality research is needed. Results from our recent study showed that several plasma concentrations of amino acids were elevated in gastric bypass patients after a mixed meal tolerance test in those who experience more satiety and in those with higher concentrations of satiety-related (anorexigenic) hormones in 3.5 hours after ingestion of the test meal. This study points in the direction that a postprandial plasma amino acid profile comparable to casein protein is associated with both increased satiety and increased concentrations of satiety-related gastrointestinal hormones. However, in healthy and obese subjects whey protein induced more effect on satiety, active GLP-1 and insulin compared to casein protein. No studies with different types of proteins have been performed in gastric bypass patients.

Objective: To investigate the effect of a test meal supplemented with casein protein in gastric bypass patients on concentrations of satiety-related plasma amino acids and satiety-related hormones and feelings of postprandial satiety and hunger compared to a test meal supplemented with whey protein.

Study design: This is a pilot study with a blinded randomized cross-over design. The recruitment will start in November 2017 and continue by approaching potential candidates consecutively.

Study population: In order to be eligible for participation in this study, subjects are women aged 18 to 65 years during their primary gastric bypass surgery 12-18 months ago at the Centre of Obesity Netherlands at the Medical Centre Leeuwarden. In total 18 subjects will be evaluated.

Intervention: During two study visits the subjects will receive 200mL lactase-containing milk with either 15 g casein protein or 15 g whey protein as supplement in a blinded randomized order.

Main study endpoint: The difference in net incremental area under the curves of the plasma concentrations of satiety-related amino acids and derivatives after ingestion of the two test meals.

Doel van het onderzoek

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Onderzoeksopzet

18 subjects will receive either casein protein or whey protein in a randomized order during two visits with a period of minimally 1 week and maximally 3 weeks between them on the same day of the week.

Each visit blood will be withdrawn through an intravenous catheter on 9 time points. An overview of the tubes is presented in Table 2. In total, 193.5 (21.5mL x 9 time points) mL blood will be withdrawn for the analyses per visit.

Onderzoeksproduct en/of interventie

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Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Female

Gastric bypass surgery at age 18-65 years

Primary gastric bypass between 12 and 18 months ago

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Follow-up is not feasible

Known allergies or intolerance to ingredients used in the intervention product

o Milk

o Soy

Medicine usage known to influence dietary uptake and/or appetite

o Antidepressants

o Antiemetics

o Laxatives

o Levodopa

o Lipid-lowering medication

o Opiates

o Prokinetics

o Systemic corticosteroids

Pregnancy

Hypo- or hyperthyroidism

Known malabsorption syndrome

Known heart failure

Known renal insufficiency or failure

Known severe hepatic disease

Known severe symptomatic post gastric bypass hypoglycaemia

Active Diabetes Mellitus or remission

Former gastric operations

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	03-01-2018

Aantal proefpersonen:	18
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	31-07-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44185
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6459
NTR-old	NTR6637
CCMO	NL61997.099.17
OMON	NL-OMON44185

Resultaten