The effect of oral ingestion of casein protein versus whey protein on plasma amino acids, satiety and anorexigenic hormones after gastric bypass surgery

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To investigate whether a test meal in gastric bypass patients with supplemented casein protein results in higher concentrations of satiety-related plasma amino acids and satiety-related hormones and leads to more postprandial satiety and less hunger…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44185

Source
ToetsingOnline

Brief title
CasWhey study: Casein protein versus Whey protein

Condition

- Other condition
- Therapeutic procedures and supportive care NEC

Synonym
fullness, satiety

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: 1. Research programma van University of Groningen/Campus Fryslan;welk gefinancieerd wordt door de provincie Fryslan. 2. Wetenschapsfonds Medisch Centrum Leeuwarden

Intervention

Keyword: Amino acids, Anorexigenic hormones, Gastric bypass surgery, Satiety

Outcome measures

Primary outcome

- To assess and compare the net incremental area under the curve of satiety-related plasma amino acids and derivatives (i.e. Alanine, Arginine, Asparagine, Glutamine, Glycine, Histidine, Lysine, Phenylalanine, Serine, Taurine, Threonine, α-aminobutyric acid) 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.

Secondary outcome

- To assess and compare the effect of the ingestion of both protein supplements in lactase-containing milk on plasma concentrations of all amino acids and derivatives, plasma concentrations of anorexigenic gastrointestinal hormones PYY and GLP-1, satiety, hunger, dumping symptoms, heart rate, blood pressure, glucose metabolism and ad libitum food intake after completion of the test meal in a randomized controlled cross over study in subjects 12-18 months after primary gastric bypass surgery.

- To assess the self-reported dietary patterns, macronutrient consumption,

energy intake, eating behaviour and physical activity measured by

questionnaires in subjects 12-18 months after primary gastric bypass surgery.

Study description

Background summary

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.

Study objective

To investigate whether a test meal in gastric bypass patients with supplemented casein protein results in higher concentrations of satiety-related plasma amino acids and satiety-related hormones and leads to more postprandial satiety and less hunger compared to a test meal with supplemented 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. The anticipated ending of the study is April 2018.

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.

Study burden and risks

Burden: Subjects will be asked to visit the hospital twice after an overnight fast apart from their routine follow-up visits. Every visit lasts approximately 5 hours. Questionnaires, a brief physical examination including weight and length will be performed. The test meal consists of lactase-containing milk with addition of either casein protein or whey protein. During the visit blood will be withdrawn 9 times via an intravenous catheter. A total amount of 193.5mL blood will be withdrawn each visit. They are not allowed to drink, eat or smoke during the visit.
Risks: blood withdrawal by placement of an intravenous catheter may cause little discomfort by inducing pain and there is a low risk of bruising and infection. The test meal and the protein supplements are commercially available and no important risks are to be expected. Although intolerance to milk or soy is an exclusion criterion, participants with unknown intolerance or allergies could experience adverse effects.
Benefit: There are no personal direct benefits for the participants.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Female
Gastric bypass surgery at age 18-65 years
Primary gastric bypass between 12 and 18 months ago

Exclusion criteria

Follow-up is not feasible
Known allergies or intolerance to ingredients used in the intervention product
Medicine usage known to influence dietary uptake and/or appetite
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

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-01-2018
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	13-07-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	18-06-2024
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 28888

Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61997.099.17