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Prevalence of dumping after bariatric surgery

Submission date
02/08/2017

Recruitment status
No longer recruiting

Registration date
03/08/2017

Overall study status
Completed

Last Edited
20/09/2023

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Gastric bypass surgery is a form of weight loss surgery (bariatric surgery) where surgical staples are used to create a small pouch at the top of the stomach. The pouch is then connected to the small intestine, missing out (bypassing) the rest of the stomach. This means it takes less food to feel full (satiety) and fewer calories are absorbed. It is very effective but can have long-term complications like dumping after a meal, when food (especially sugar) moves too quickly from the stomach into the small intestines. The complaints of dumping can be dizziness, confusion, a desire to lie down, nausea, sweating and palpitations. Two types of dumping have been described: early dumping and late dumping. The mechanisms behind dumping are not fully understood, but it can be result of low blood pressure or low blood glucose. Also, the percentage of people suffering from early and late dumping are not yet known. Additional to the dumping, weight loss after gastric bypass surgery is at risk of weight regain after a while. Furthermore, this weight loss is associated with the unwanted loss of muscle mass and nutritional deficits. All could be improved by greater satiety and targeted nutrition. Amino acids are the building blocks of proteins. In healthy and obese people, circulating amino acids in the blood have been linked with both satiety (fullness) and the release of hormones. This effect has not yet been investigated in patients with bariatric surgery. This effect could be different in those patients because of the altered anatomy and different absorption of amino acids. The best way to diagnose dumping is the Mixed Meal Tolerance Test (MMTT). During the MMTT blood samples are collected over time before and for 3.5 hours after eating a standardized mixed meal. Furthermore, during the MMTT patients are asked about their level of satiety, hunger and dumping complaints. The collected blood samples can also be used for measuring hormones, amino acids and other blood parameters that could be related to satiety and hunger. The aim of this study is to investigate the presence of dumping after gastric bypass surgery and to get more insight into the mechanisms behind early and late dumping. Changes in satiety, hormones, amino acids and other blood parameters are also measured.

Who can participate?
Patients aged between 18 and 75 who underwent gastric bypass surgery between 2008 and 2011 at the Center of Obesity Netherlands at the Medical Center Leeuwarden

What does the study involve?
Participants are asked to visit the hospital after an overnight fast apart from their routine follow-up visits. A visit lasts about 5 hours. Questionnaires are completed and a brief physical

examination including weight and length is performed. All participants undergo a Mixed Meal Tolerance Test (MMTT). Blood samples are collected before and at 10, 20, 30, 60, 90, 120, 150, 180 and 210 minutes after eating the mixed meal. Satiety, hunger and dumping symptoms are assessed every 30 minutes.

What are the possible benefits and risks of participating?
There are no personal direct benefits for the participants. Blood withdrawal may cause little discomfort and there is a low risk of bruising and infection. Participants can get complaints of dumping during the MMTT, but this is temporary.

Where is the study run from?
Medical Center Leeuwarden, Leeuwarden (Netherlands)

When is the study starting and how long is it expected to run for?
January 2013 to May 2015

Who is funding the study?
Medical Center Leeuwarden, Leeuwarden (Netherlands)

Who is the main contact?
Dr Marloes Emous

Contact information

Type(s)
Scientific

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Protocol serial number
NL41604.099.12

Study information

Scientific Title
Hyperinsulinemic hypoglycemia, satiety and other blood parameters during a Mixed Meal Tolerance Test in patients after gastric bypass surgery

Study objectives
The primary objective is to assess the prevalence of hyperinsulinemic hypoglycemia in patients after gastric bypass surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The regional medical ethics committee (Regionale Toetsingscommissie Persoonsgebonden Onderzoek; RTPO) in Leeuwarden

Study design
Observational cross-sectional study

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
Hyperinsulinemic hypoglycaemia, nesidioblastosis, late dumping, satiety, metabolism

Interventions
After an overnight fast, all subjects will undergo a Mixed Meal Tolerance Test (MMTT) consisting of 200mL Ensure® Plus (Abbott Laboratories, North Chicago, IL, USA) containing 300 kcal, 12.5 g protein, 40.4 g carbohydrate, 9.84 g fat and 154.86 g water. Questionnaires, a brief physical examination including weight and length will be performed. During the visit blood will be withdrawn 10 times via an intravenous catheter.

Primary study parameters:
To investigate the prevalence of hyperinsulinemic hypoglycemia after gastric bypass surgery and to get more insight in mechanisms behind (early and late) dumping. Also, complaints of dumping syndrome will be assessed with various questionnaires.

A serum glucose below 3,3 mmol/L combined with complaints of hypoglycemia is defined as symptomatic late dumping. A serum glucose below 3,3 mmol/L without complaints is defined as asymptomatic late dumping.
A serum glucose above 3,3 mmol/L is defined a no late dumping.

An increase in pulse-rate > 10 beats/minute or an increase in hematocrit > 3% before MMTT until 30 minutes after a meal with complaints of dumping is defined as symptomatic early dumping. An increase in pulse-rate > 10 beats/minute or an increase in hematocrit > 3% before MMTT untill 30 minutes after a meal without complaints of dumping is defined as asymptomatic early dumping. Changes in pulse-rate < 10 beats/minute or a change in hemotocrit < 3% is defined as no early dumping.

Secondary study parameters:
To investigate the postprandial change and associations of satiety scores, plasma gastrointestinal hormones, plasma amino acids and other blood parameters after gastric bypass surgery.

Intervention Type
Other

Primary outcome(s)
The prevalence of hyperinsulinemic hypoglycemia after gastric bypass during a 3.5 hour Mixed Meal Tolerance Test (MMTT). Symptoms will be assessed by the Dumping Severity Score and other questionnaires every 30 minutes and blood collection will be performed at baseline and 10, 20, 30, 60, 90, 120, 150, 180 and 210 minutes after the start of the test meal.

Key secondary outcome(s))
1. Sensitivity and specificity of the Dumping Severity Score and other questionnaires for early and late dumping assessed every 30 minutes during the 3.5 hour MMTT
2. Plasma incretin (i.e., gastrointestinal hormone) concentrations during the 3.5 hour MMTT with blood collection at baseline and 10, 20, 30, 60, 90, 120, 150, 180 and 210 minutes after the start of the test meal
3. Plasma amino acid concentrations during the 3.5 hour MMTT with blood collection at baseline and 10, 20, 30, 60, 90, 120, 150, 180 and 210 minutes after the start of the test meal
4. Other blood parameters during the 3.5 hour MMTT with blood collection at baseline and 10, 20, 30, 60, 90, 120, 150, 180 and 210 minutes after the start of the test meal
5. Satiety scores, measured every 30 minutes using a visual analogue scale (VAS) during the 3.5 hour MMTT

Completion date
24/05/2015

Eligibility

Key inclusion criteria
1. Patients who underwent primary Roux-en-Y gastric bypass surgery between 2008 and 2011
2. Age between 18 and 75 years
3. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
44

Key exclusion criteria
Patients with diabetes mellitus

Date of first enrolment
01/02/2013

Date of final enrolment
24/05/2015

Locations

Countries of recruitment
Netherlands

Study participating centre
Medical Center Leeuwarden
Henri Dunantweg 2
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Sponsor information

Organisation
Medical Center Leeuwarden

ROR
https://ror.org/0283nw634

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Medical Center Leeuwarden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be shared with the journal only for verification and review prior to publication upon their request. Other requests will not be met. Data is coded and not traceable to a patient.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2018		Yes	No
Results article	results	01/02/2021	22/10/2020	Yes	No
Results article	bile acid kinetics	15/01/2021	20/09/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes