Prevalence of dumping after bariatric surgery

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Primary Objective: Prevalence of hyperinsulinemic hypoglycemia after gastric bypass.Secondary Objective(s): Determination of diagnostic acuurace of a dumping questionnary (Bepaling modified Sigstad score).Descriptive research to the value of CGMS as...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON36872

Source
ToetsingOnline

Brief title
Prevalence of dumping

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
hyperinsulinemic hypoglycaemia, late dumping, nesidioblastosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bariatric surgery, dumping, Mixed meal Tolerance Test

Outcome measures

Primary outcome

Prevalence of hyperinsulinemic hypoglycemia after gastric bypass

A serum glucose below 3,3 mmol/L combined with complaints of hypoglydcemia 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 untill 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 hemotocrittocriet < 3% is defined as no early dumping.

Secondary outcome

Sensitivity and specificity of the modified Sigstad score for early and late dumping.

Descriptive research to the value of Coninuous Glucose Monitoring System in

the Mixed Meal Tolerance Test.

Determination of the extensiveness a the MMTT can be reduced in a more

practical test for diagnosing dumping

Study description

Background summary

Bariatric surgery, especially gastric bypass, has a few complications in the long term. One of these complications is dumping. A few hours after a meal patients can get symptoms which can be explained by dumping. Two types of dumping are described in literature:
Early dumping; based on undigested food which enter directly in the short bowel. Therefore fluid enters the short bowel from the circulation and patients develop a hypovolemia. this started within an hour after a meal.
Late dumping; based on an increased insulin and therefore hypoglycemia (hyperinsulinemic hypoglycemia). Cause of this increase in insulin is probably due to positive and nagative feedback mecahnisms to the pancreas are changing after bariatric surgery. The precise mechanism behind these changes are not fully understood.
The incidence and prevalence of late dumping (or hyperinsulinemic hypoglycemia) are not known. In literature the prevalence of severe hypoglycemia is estimated on < 1%. Severe hypoglycemia is defined as hypoglycemia for which treatment in hospital is necessary. Possibly the prevalence of milde dumping is about 30%.

The gold standard for the diabnose of hyperinsulinemic hypoglycemia is the Mixed Meal Tolerance Test. A standardised meal of fat, protein and carbohydrates give better hyperinsulinec respons than the older glucose tolerance test. on standardised moments blood samples are taken, every 30 minutes after the meal. Sometimes the exact lowest measrurement of glucose can be missed. Probable a continu glocose monitoring system (CGMS) gives us the opportunity to see the exact time of dipping in glucose. A disadvantage of the MMTT is the extensiveness of the test. Probably it is possible with help of the continuus glucose mointroing system we can develop a more simple test.

To review complaints of dumping Sigstad developped a questionnary. The diagnostic Ter beoordeling van dumping klachten zijn ook vragenlijsten ontwikkeld. De Sigstad score is hiervoor de meest gebruikte vragenlijst. Diagnostische accuracy is never validated in a bigger population of bariatric patients.

Study objective

Primary Objective:
Prevalence of hyperinsulinemic hypoglycemia after gastric bypass.

Secondary Objective(s):
Determination of diagnostic acuurace of a dumping questionnary (Bepaling modified Sigstad score).
Descriptive research to the value of CGMS as a tool in the MMTT.
Determination of the extensiveness a the MMTT can be reduced in a more practical test.

Study design

A cross-sectional study.

Study burden and risks

Testpersons may not eat from the evening before the test. The whole test takes 5 hours and is performed on the ward for diagnostic blood puncturesof the Medical Center Leeuwarden.
Testpersons get an intravenous excess and a part of the patients get a Continuous Glucose Monitoring System in the skin of their abdomen. In total 12 bloodsamples are taken.
Testpersons can get complaints of hypoglycemia, but this is temporarly.

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

Patients who underwent bariatric surgery between 2008 and 2011
Patients who participated and filled out a questionnary in earlier research
Informed Consent

Exclusion criteria

Patients with diabetes mellitus
No Informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	24-01-2013
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL41604.099.12