Bariatric procedures and changes in gut hormones and gastric passage

Published: 02-11-2017
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To assess and compare the gastric emptying rate and gut hormone levels between patients one year after standard RYGB (S-RYGB), B-RYGB and EP-RYGB.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON44151

Source
ToetsingOnline

Brief title
BIP-study

Condition

- Gastrointestinal therapeutic procedures

Synonym
Gastric emptying, hormonal changes

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: Bariatric surgery, Gastric emptying, Incretins, Roux-en-Y gastric bypass

Outcome measures

Primary outcome

Gastric emptying rate and gut hormone levels in patients one year after S-RYGB,

B-RYGB and EP-RYGB.

Secondary outcome

Excess weight loss (%EWL)

Study description

Background summary

The most performed type of bariatric surgery performed in Europe is de the Roux-en-Y gastric bypass (RYGB). It*s an effective treatment of morbid obesity, with long-term weight loss and improvement of obesity related comorbidities. The mechanisms that are involved remain not fully understood. After RYGB the stomach volume is decreased and satiety levels often increase probably due to changes in gut hormones. Gastric emptying is often mentioned as mechanism effecting weight loss by its role in the release of these hormones. A fast pouch emptying in patients with poor weight loss after RYGB is found.
To improve the short and long term weight loss after RYGB the technique of the operation is modified and studied. Banding of the gastric pouch (B-RYGB) and creating a longer and narrower pouch, an extended pouch RYGB (EP-RYGB) may, following physical laws, delay pouch emptying resulting in more weight loss after surgery. The more gradual emptying may induce a longer period of gut hormone secretion and therefore increase satiety.

Study objective

To assess and compare the gastric emptying rate and gut hormone levels between patients one year after standard RYGB (S-RYGB), B-RYGB and EP-RYGB.

Study design

A prospective trial in which gastric emptying rate an gut hormone levels are measured in patients one year after S-RYGB, B-RYGB and EP-RYGB.

Study burden and risks

Participation in this study implies extra visits to the participating hospital.
The absorbed effective dose equivalent of radiation falls into the lowest risk category.

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

- Age > 18 years
- Patient underwent a standard RYGB (S-RYGB), B-RYGB or EP-RYGB and is a mean responder (clinic mean Excess Weight Loss +/- 10% or mean Total Body Weight Loss +/- 5%).
- Patient is able to adhere to the study visit schedule and protocol requirements
- Patient is able to give informed consent and the consent must be obtained prior to any study procedures
- Patient had a follow-up period of at least one year after S-RYGB, B-RYGB or EP-RYGB without

any complications

Exclusion criteria

- Binge-eating or associated eating disorder
- Active drug or alcohol addiction
- Pregnancy and when giving breast feeding
- Gluten allergy
- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, prokinetics, theophylline, calcium blocking agents, opioids)
- Endocrine disease influencing gastric emptying (diabetes mellitus, hyper- or hypothyroidism)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	02-11-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	07-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	28-08-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL62399.091.17