

Bariatric procedures and changes in incretines and gastric emptying

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To assess gastric emptying rates and incretin levels in good and bad responders two years after LRYGB and LSG. Additionally, gastric emptying rate is assessed before and after placement of the DJBL in overweight patients with T2DM.

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

Summary

ID

NL-OMON40704

Source

ToetsingOnline

Brief title

BIG-study

Condition

- Gastrointestinal therapeutic procedures

Synonym

Gastric emptying, Hormonal changes, Transit time

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: Duodenal-jejunal bypass liner, Gastric emptying, Incretins, Roux-en-Y gastric bypass

Outcome measures

Primary outcome

Gastric emptying rate and incretin levels two years after LRYGB and LSG, and gastric emptying before and 1 month after DJBL implantation.

Secondary outcome

- Weight loss/ excess weight loss two years after Roux-en-Y Gastric Bypass and Sleeve Gastrectomy
- Quality of life two years after Roux-en-Y Gastric Bypass and Sleeve Gastrectomy
- Quality of life before and one month after implantation of the duodenal-jejunal bypass liner

Study description

Background summary

The two most performed types of bariatric surgery in the Netherlands are the Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) and the Laparoscopic Sleeve Gastrectomy (LSG). Additionally, less invasive methods to control overweight and type 2 Diabetes Mellitus (T2DM) are available, such as the duodenal-jejunal bypass liner (DJBL).

The mechanism of bariatric procedures is still not fully understood. Stomach volume is decreased and satiety levels often increase, probably due to changes in incretin levels. Passage of foods through the gastrointestinal tract are altered.

Patients response on the different bariatric procedure varies widely and it is difficult to predict which patient responds well. It is unclear if patients who have successful excess weight loss (EWL) two years after surgery have different Gastric emptying (GE) rates than unsuccessful patients. Additionally, it is

unclear if incretin levels differ between successful and unsuccessful patients. Gastric emptying after placement of a DJBL is unclear. However, changes in incretin levels before and after DJBL implantation are already demonstrated in earlier studies.

We hypothesize that GE of solid food is increased in good responders in terms of weight loss compared to bad responders after LRYGB and LSG. Additionally we hypothesize that different incretin levels are observed in good and bad responders. Regarding the DJBL we hypothesize that GE will decrease after implantation compared to GE prior to implantation.

Study objective

To assess gastric emptying rates and incretin levels in good and bad responders two years after LRYGB and LSG. Additionally, gastric emptying rate is assessed before and after placement of the DJBL in overweight patients with T2DM.

Study design

A prospective trial in which gastric emptying rate and incretin levels are measured in good and bad responders two years after LRYGB and LSG. Gastric emptying rate is assessed before and after placement of the DJBL in overweight patients with T2DM.

Study burden and risks

Patients will undergo a gastric emptying study two years after bariatric surgery, or before and one month after implantation of the DJBL.. The nuclear radiation burden is 0.5 mSv for LRYGB and LSG patients, and 1.0 mSv (2 times 0.5 mSv) for patients receiving the DJBL.. For LRYGB and LSG patients this burden is comparable with a transatlantic flight (0.4 mSv) and for patients receiving the DJBL this is half of the annual national background radiation in the Netherlands (2 mSv/ year).

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

I.

Patients who are approaching their two years follow-up after Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) and Laparoscopic Sleeve Gastrectomy (LSG) are eligible for inclusion. The patients will be arranged in one of the following four groups according to the Reinhold*s criteria:;- Good responders (EWL > 50%) two years after RYGB

- Bad responders (EWL < 25%) two years after RYGB

- Good responders (EWL > 50%) two years after LSG

- Bad responders (EWL < 25%) two years after LSG;II.

Patients who are eligible for duodenal-jejunal bypass liner implantation. These patients have been diagnosed with type 2 and a BMI 28-45 kg/m2.

Exclusion criteria

- Binge-eating or associated eating disorder

- Active drug or alcohol addiction

- 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). T2DM is not an exclusion criteria for patients receiving the DJBL because

T2DM is a requirement for receiving the DJBL. Additionally, changes in GE rate will be

determined 1 month after implantation. No significant changes in GE rate will be expected in this time period caused by their T2DM

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 08-05-2015

Enrollment: 32

Type: Actual

Ethics review

Approved WMO

Date: 08-10-2014

Application type: First submission

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

CCMO

ID

NL50111.091.14