Changes in incretines and bile acids after Roux-en-Y Gastric Bypass.

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1. comparison between pre- and postoperative serum levels incretines and bile acids (after RYGB).2. comparison between S-RYGB and LBPL-RYGB with respect to incretines and bile acids.

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

Summary

ID

NL-OMON41757

Source
ToetsingOnline

Brief title
Incretine changes after RYGB

Condition

- Gastrointestinal therapeutic procedures

Synonym
Hormonal changes, Incretin levels

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bile acids, Incretines, Roux-en-Y Gastric Bypass

Outcome measures

Primary outcome

Pre- and postoperative (after 4 weeks) measurement of incretin and bile acid

concentration in patients that undergo a RYGB (S-RYGB and LBPL-RYGB)

Secondary outcome

nvt

Study description

Background summary

Obesity is an increasing world wide problem. Moreover, the increase in patients who are considered morbidly obese is even higher (Sturm et al, Healt Aff 2004). Conservative approaches such as diets or medication are unsuccessful in the majority of the patients. Additionally, (morbid) obesity leads often to cardiovascular diseases, such as hypertension, dyslipidemia and type 2 diabetes (T2DM). When patients need insulin to regulate their glucose levels, their weight is even more difficult to control. Therefore, bariatric procedures are increasingly performed, with over 8.000 procedures in the Netherlands in 2013. 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).

Within the LRYGB there are different variants available. In a recently initiated randomized controlled trial (RCT) from our centre, a comparison between two variants of RYGB was performed. In this RCT our standard RYGB (s-RYGB: alimentary limb (AL) of 150cm; biliopancreatic limb (BPL) of 75cm) was compared with a RYGB with an long BPL (LBPL-RYGB: AL of 75cm and a BPL of 150cm). Not yet published outcomes of this study showed 10% more excess weight loss (EWL) in favour of the LBPL-RYGB after 12 months follow-up. Additionally, the LBPL-RYGB might have a slight advance on reduction of T2DM and the number of complications are comparable.

However, the exact mechanism of action 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 after RYGB. A possible explanation might be found in different levels of incretins (such as GLP-1, PYY and ghrelin) and bile acids (FGF-19 and FGF-21) after bariatric surgery.

We hypothesize that incretin and bile acid levels are different between patients receiving a S-RYGB and LBPL-RYGB.

Study objective

1. comparison between pre- and postoperative serum levels incretines and bile acids (after RYGB).
2. comparison between S-RYGB and LBPL-RYGB with respect to incretines and bile acids.

Study design

A prospective randomized trial in which incretine and bile acid concentrations will be measured.

Study burden and risks

nvt

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

-General guidelines for bariatric surgery according to Fried (Fried et al, Obes Surg 2007).
-Age > 18 years
-Patients must be able to adhere to the study visit schedule and protocol requirements
-Patients must be able to give informed consent and the consent must be obtained prior to any study procedures
-Patients who are planned for a LRYGB

Exclusion criteria

-Binge-eating or associated eating disorder
-Active drug or alcohol addiction
-Pregnancy and when giving breast feeding
-A medical history of bariatric surgery
-Patients with a language barrier which can inhibit patients to follow the correct medical advice
-Any kind of genetic disorder that can inhibit patients to follow the correct medical advice

Study design

Design

Study type: Observational invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-10-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	29-12-2014
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	ID
CCMO	NL51154.091.14