Faecal reference values after Roux-en-Y gastric bypass

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28438

Source
NTR

Health condition

Roux-en-Y Gastric Bypass, morbid obesity, faecal, calprotectin, elastase, alpha-1-antitrypsin.

Sponsors and support

Primary sponsor: Slotervaart Hospital

Intervention

Outcome measures

Primary outcome

Determination of reference values of faecal calprotectin, elastase-1 and alpha-1-antitrypsin after RYGB

Study description

Background summary

The aim of this study is to determine reference values of faecal calprotectin, elastase-1 and alpha-1-antitrypsin after Roux-en-Y Gastric Bypass procedure (RYGB).

The prevalence of morbid obesity, and its associated comorbidities, is increasing worldwide. Bariatric surgery is the most effective long-term solution of morbid obesity, RYGB being one of the most performed procedures with a presumed restrictive and malabsorptive effect.

RYGB changes the anatomy of the gastro-intestinal tract. It affects the digestion and absorption of food in the bowel, which makes it likely to also affect the composition of faeces. In clinical practise, faecal measurements are used to diagnose, rule out or monitor the course of diseases.

Calprotectin is widely used as a diagnostic and prognostic marker of inflammatory bowel diseases. Faecal elastase-1 can be determined to diagnose and monitor patients with exocrine pancreatic insufficiency. Faecal alpha-1-antitrypsin is used to diagnose a protein-losing enteropathy.

A recent study showed significant changes in the faecal calprotectin and elastase-1 concentration in 7 patients after RYGB, compared to obese controls. To determine faecal reference values after RYGB keeps non-invasive faecal diagnostic tests in use for these patients and may contribute to better understanding of gut function and adaptation after RYGB.

Study objective

Because of modified anatomy of the gastro-intestinal tract after RYGB, which affects digestion and absorption of food, it is hypothesized that faecal composition after RYGB is also changed.

Study design

Between 12 and 24 months post-operative.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

-Patients who are 12-24 months post-RYGB.

Exclusion criteria

- Patients who have diarrhoea at the time of faeces collection

- Patients who use a PPI or NSAID, without the possibility to discontinue this medication for at least 3 days

- Patients with an acute or chronic disease of stomach, intestine or pancreas which may influence the measurements made in this study.

E.g.: inflammatory bowel disease, malignancy of stomach, intestine or pancreas, chronic pancreatitis, chronic bowel infection, resection of stomach or bowel other than RYGB, radiotherapy with the gut laying within the ablated area, systemic disease which influences the gastro-intestinal tract (e.g. systemic sclerosis)

Not excluded are patients with e.g. cholecystectomy, bacterial gastro-enteritis or acute pancreatitis, provided that patients are fully recovered.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2014
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-08-2014
Application type:	First submission

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
NTR-new	NL4610

Register	ID
NTR-old	NTR4761
Other	METC Slotervaartziekenhuis : P1437

Study results

Summary results
N/A