Faecal reference values after Roux-en-Y gastric bypass

Published: 06-07-2014
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The primary objective is the determination of faecal reference values of calprotectin, elastase and alpha-1-antitrypsin after RYGBP.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON40926

Source
ToetsingOnline

Brief title
N.V.T.

Condition

- Gastrointestinal inflammatory conditions

Synonym
gastric bypass

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: Stichting Klinisch Wetenschappelijk Onderzoek Slotervaartziekenhuis (SKWOSZ)

Intervention

Keyword: Faeces, Reference values, Roux-en-Y gastric bypass

Outcome measures

Primary outcome

The determination of faecal reference values of calprotectin, elastase and

alpha-1-antitrypsin after RYGBP.

Secondary outcome

Not applicable.

Study description

Background summary

The Roux-en-Y gastric bypass (RYGBP) changes anatomy and function of the gastrointestinal system. This influences digestion and absorption of food, and is therefore likely to influence the structure of the faeces as well. In the clinic, certain faecal values are used to diagnose or rule out certain diseases, or for follow-up. Calprotectin is upcoming as a marker for inflammatory bowel disease. Elastase is a marker for pancreas insufficiency. Alpha-1-antitrypsin is used in the diagnosis of protein-losing enteropathy. A recent study showed that the faecal values of calprotectin and elastase after RYGBP differed significantly from the values in healthy controls.

Study objective

The primary objective is the determination of faecal reference values of calprotectin, elastase and alpha-1-antitrypsin after RYGBP.

Study design

Observational cross-sectional study for which a single faeces sample is obtained from patients who are at least 1 year after RYGBP.

Study burden and risks

The burden and risks for the participants are minimal. The patient has to

collect a single sample of faeces and send it to the hospital. No extra visits or investigations are needed.

Contacts

Public
Slotervaartziekenhuis

Louwesweg 6
Amsterdam 1066EC
NL
Scientific
Slotervaartziekenhuis

Louwesweg 6
Amsterdam 1066EC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients who underwent RYGBP one to two years ago.

Exclusion criteria

- Diarrhea at the time of faeces collection
- Use of proton pump inhibitors or NSAIDs and unable to stop.

- An acute gastrointestinal disease at the time of participation or a chronic gastrointestinal disease in the medical history.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-10-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	06-07-2014
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL49803.048.14