Macro- and microscopic mucosal characteristics of the biliopancreatic limb and excluded stomach after Roux-en-y gastric bypass

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Determination of microbiological, macro and microscopic / histological characteristics after RYGB, mainly targeted at identifying inflammatory characteristics, bacterial (over) growth and / or atrophy / metaplasia in the excluded stomach and the...

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

Summary

ID

NL-OMON44359

Source ToetsingOnline

Brief title MACARENA

Condition

• Gastrointestinal disorders

Synonym Dysplasia, metaplasia: abnormality/changes in the tissue/cell

Research involving

Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis

Source(s) of monetary or material Support: Stichting klinisch wetenschappelijk onderzoek Slotervaartziekenhuis

Intervention

Keyword: blind loop, mucosa, Roux-en-y

Outcome measures

Primary outcome

Determination of changes in macroscopic and histological characteristics of the

excluded stomach and blind loop after RYGB

Secondary outcome

N.A.

Study description

Background summary

The Roux-and-Y gastric bypass (RYGBP) changes the anatomy and function of the gastrointestinal tract. A blind (Y-) loop (duodenum and proximal jejunum) is created and a large part of the stomach diverted (excluded). This affects the digestion and absorption of food in the intestine and causes histological changes in the gastrointestinal tract. Histological examination of the blind loop after RYGB has not been performed so far and histological changes in the excluded stomach including the long-term consequences are insufficiently known.

Study objective

Determination of microbiological, macro and microscopic / histological characteristics after RYGB, mainly targeted at identifying inflammatory characteristics, bacterial (over) growth and / or atrophy / metaplasia in the excluded stomach and the blind loop (duodenum and proximal jejunum).

Study design

Cross-sectional study.

The inflammatory, macro and microscopic histological characteristics are described by endoscopic image and biopsy obtained via transgastric ERCP or duodeno gastroscopy. Signs and severity of inflammation, atrophy and metaplasia

are described.

Study burden and risks

Biopsies of the excluded stomach and the blind loop are taken in patients who have to undergo a laparoscopic assisted ERCP because of occluded choledochus stones. The additional risks of participation in this study consist of possible complications due to the biopsy (bleeding, perforations). The overall percentage of complications in a normal oesophago-gastro-duodenoscopy (OGD) (incl biopsy) is 0.009-0.13% with a mortality of 0.0009-0.004%, a perforation risk of 0.0009% and a bleeding risk after biopsy of 0.002%. Participation in this study thus gives a minimal additional risk on top of the already existing risks of the endoscopy and laparoscopy.

There are no other additional surveys or visits required. There is no benefit for the subject to be expected.

Contacts

Public Slotervaartziekenhuis

Louwesweg 6 Amsterdam 1066 EC NL **Scientific** Slotervaartziekenhuis

Louwesweg 6 Amsterdam 1066 EC NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Patients after Roux-en-y gastric bypass in need for endoscopic retrogate cholangio and pancreaticography.

Exclusion criteria

- Chronic gastrointestinal disease other than cholangitis
- No signed informed consent

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

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NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	26-09-2017
Enrollment:	15
Туре:	Actual

Ethics review

Approved WMO	
Date:	23-08-2017
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
ССМО	NL62610.048.17

Study results

Date completed:	23-01-2019
Actual enrolment:	21