Size Measurements of the Gastric Pouch and Gastroenterostomy on CT and Upper GI Series after Roux-en-Y Gastric Bypass Surgery and Sleeve Gastrectomy

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To determine whether UGI series is a feasible technique for 2D and 3D gastric pouch and gastroenterostomy size measurements after Roux-en-Y gastric bypass surgery.

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

Summary

ID

NL-OMON47864

Source
ToetsingOnline

Brief title
PAGSAR (Pouch And Gastroenterostomy Size After RYGB and SG)

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
Dilation of the gastric pouch and gastroenterostomy or gastric sleeve

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Geen extra kosten verbonden aan het onderzoek behoudens tijd van onderzoekers en artsen (vrijwillig)

Intervention

Keyword: Bariatric surgery, Gastric pouch, Gastric sleeve, Size

Outcome measures

Primary outcome

Main study parameters are pouch volume and gastroenterostomy area and diameter

and sleeve volume on CT scan and UGI series.

Secondary outcome

nvt

Study description

Background summary

Morbid obesity is a global and imminent health issue. The Roux-en-Y gastric bypass (RYGB) and sleeve gastrectomy (SG) are effective and sustainable methods for weight loss. Although the advantages of bariatric surgery have been widely shown, insufficient weight loss, weight regain and malnutrition are important adverse long-term outcomes. It has been discussed if, and to what extent gastric pouch size and gastroenterostomy size or sleeve size influence the outcomes of bariatric surgery in terms of weight loss. The inability of revealing a relationship between pouch or anastomosis size in RYGB and sleeve size in SG and weight loss may be due to the (suboptimal) methods that have been used for size measurements. Computed tomography (CT) and upper gastrointestinal (UGI) series have been used for size measurements after RYGB or SG surgery. Although size measurements can be accurately performed on CT scans, the use of UGI series has several advantages over CT, such as lower costs, easier accessibility and lower radiation dose. We aim to validate an optimized UGI examination for size measurements of the gastric pouch and gastroenterostomy after RYGB or SG surgery.

Study objective

To determine whether UGI series is a feasible technique for 2D and 3D gastric pouch and gastroenterostomy size measurements after Roux-en-Y gastric bypass surgery.

Study design

This study will be a prospective pilot study. Size measurements on a newly developed standardized method using UGI examination (including fluoroscopy) will be compared to CT as a gold standard.

Study burden and risks

In this pilot study, subjects will receive an additional radiation dose of about 2 mSv. On average, an acute dose of 10 mSv of this type of radiation leads to an additional risk of cancer of about 1 in 1750 (~1 in 2000 for males, ~1 in 1500 for females) for a 50-year old subject, based on the linear no threshold model. The standard diagnosing tool for inventorying weight regain after RYGB is the CT scan. However, UGI examination has several advantages over CT that could prove to be useful for pouch and gastroenterostomy measurements.

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

The patient should have undergone laparoscopic RYGB or SG surgery (standard procedure);
The patient must have a CT scan planned, for example for evaluation of upper abdominal complaints or weight regain.

Exclusion criteria

The patient is suspected to have a leakage of the gastric pouch, gastric sleeve or gastroenterostomy;
The patient has an age below 18;
The patient is incompetent to decide;
The patient is pregnant or gives breast feeding;
One or more scans have insufficient scan quality;
The patient has a contra-indication for the administration of IV contrast;
The patient is not able to tolerate effervescent granules.

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):	02-07-2018
Enrollment:	24

Type:	Actual

Ethics review

Approved WMO Date:	22-02-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-05-2018
Application type:	Amendment
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	NL60384.091.16