Abdominal CT Angiography to Visualize Mesenteric Vessels for Diagnosing Internal Herniation after Roux-en-Y Gastric Bypass Surgery

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

Summary

ID

NL-OMON42091

Source
ToetsingOnline

Brief title
CTA for Internal Herniation after RYGB

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
Internal constriction of the small bowels

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CT angiography, Internal hernia, Roux-en-Y gastric bypass

Outcome measures

Primary outcome

Primary study endpoints are the assessments of the arterial abdominal angiogram

and mesenteric arterial mapping in relation to the outcome of the diagnostic

laparoscopic surgery.

Secondary outcome

Secondary study parameters are the assessments of the conventional CT abdomen,

the CT angiogram and the mesenteric arterial mapping, the comparison of these

images and the comparison of these images to the surgical outcome. The

sensitivity and specificity of both CT scans to diagnose an internal herniation

will be calculated

Study description

Background summary

Morbid obesity, defined as a body mass index (BMI) of over 40 kg/m2, is globally an imminent health threat. Conservative therapies do often not yield the desired result. Bariatric surgery includes several interventions that are performed on patients with morbid obesity, like gastric bypass surgery. The number of bariatric surgeries annually is estimated to be around 500,000 worldwide; about half of these are gastric bypass surgeries. In the Netherlands, the most common performed bariatric intervention is the Roux-en-Y gastric bypass (RYGB). An important long-term complication of this surgery is

internal herniation, a condition in which a part of the GI tract is herniated through an opening in the mesentery made during RYGB surgery. Incidence of internal herniation is 1-5%. Conventional abdominal CT examination is often not conclusive about the presence of internal herniation. When internal herniation is still highly suspected after abdominal CT examination (but not necessarily confirmed), the patient is subjected to diagnostic laparoscopic surgery. Contrary, a negative abdominal CT scan does not exclude internal herniation in all patients. This pleads for the development or exploitation of new techniques that might aid in the diagnosis of complications after RYGB surgery. Since the anatomy of GI tract is altered when internal herniation is present, visualizing the mesenteric vasculature may aid in the diagnosis of this complication after RYGB surgery. This study aims to confirm the feasibility and superiority of diagnosing internal herniation using CT examination of the mesenteric arteries over conventional CT examination.

Study objective

The primary objective is to determine whether abdominal arterial CT angiography is a feasible technique for diagnosing internal herniation after RYGB surgery. Secondary, it is examined whether arterial angiography of the mesentery is superior over conventional CT examination with oral and IV contrast in the venous phase.

Study design

This study will be a prospective pilot study, in which the outcomes of both the conventional CT examination and abdominal angiogram are compared to the outcome of diagnostic laparoscopy as gold standard.

Study burden and risks

In this pilot study, study subjects will receive an additional effective radiation dose of about 10 mSv. On average, an acute dose of 10 mSv 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. However, when the mesenteric artery mapping proves to be feasible and superior, many unnecessary diagnostic laparoscopic surgeries will be prevented (along with their complications and risks).

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

Patient have underwent laparoscopic RYGB surgery (the standard procedure with closing of mesenteric openings) at least half a year ago;
Patient has abdominal pain at least three days in a row
Patient is highly suspected for internal herniation judged by the surgeon and based on weight loss and pain (location of the pain, the intervals between pain, the relation to food intake).

Exclusion criteria

Age < 18 years;
Patient is incompetent to decide;
Patient is in emergency setting and requires imminent surgery;
Other abdominal pathology or prior large abdominal surgery;
Previous surgery for internal herniation;
Previous surgery involving the RYGB
One or both CT scans have insufficient scan quality;
The patient will not be subjected to diagnostic laparoscopic surgery.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-09-2016
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2016
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	NL52257.091.15

Study results

Date completed:	01-01-2018
Actual enrolment:	12