The comparison of the diagnostic yield of low dose abdominal CT versus normal dose abdominal CT in bariatric patients with abdominal pain

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Primary Objective: • Compare the diagnostic performance of the low dose abdominal CT scan to the normal dose abdominal CT scan in diagnosing causes of abdominal pain.Secondary Objectives:• Compare the diagnostic performance of diagnosing internal...

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal stenosis and obstruction
Study type	Observational invasive

Summary

ID

NL-OMON56694

Source
ToetsingOnline

Brief title
HOUNSFIELD study

Condition

- Gastrointestinal stenosis and obstruction

Synonym
bowel distortion, internal herniation

Research involving
Human

Sponsors and support

Primary sponsor: Spaarne Gasthuis

Source(s) of monetary or material Support: Spaarne Gasthuis Academy

Intervention

Keyword: Abdominal pain, Bariatric surgery, Low dose CT

Outcome measures

Primary outcome

The first aim of the study is to see whether abnormalities are generally seen equally well (non-inferiority) on the low dose abdominal CT scan compared to the normal abdominal CT scan.

Secondary outcome

The second aim of the study is to compare whether an internal herniation is seen equally well (non-inferiority) on the abdominal low dose CT scan compared to the normal abdominal CT scan.

An additional endpoint will be the comparison in quality between the normal dose CT scan and the low dose CT scan.

Study description

Background summary

The number of bariatric surgeries performed is increasing due to the growing incidence of obesity in the general population. Bariatric surgery (BS) has many benefits, including weight loss, and proven reduction of comorbidities such as hypertension, diabetes, hyperlipidemia, obstructive sleep apnea, joint complaints and gastroesophageal reflux disease. However, research has shown that 33% of patients experience (chronic) abdominal pain after BS. This leads to frequent visits of BS patients to the emergency room and outpatient clinic. During these visits, extensive diagnostic testing is often required to determine the cause. The most commonly used tests in this case is the abdominal CT scan. In our own research at the Spaarne Gasthuis on the patient population presenting with abdominal pain complaints after BS, we found that 66% of patients undergo at least one abdominal CT scan (data not yet published).

Moreover, some patients even receive up to six CT scans in a single year. Recurrent CT scans may impose a health risk in this population due to the link between radiation exposure and increased risk for malignancy (1, 2). Especially abdominal and pelvis CT scans account for 50% of the collective CT dose (3). In addition, in our own recent study, we saw that 90 percent of patients with abdominal pain complaints were female with an average age of 47.2 years This means that a substantial part of CT receiving patients were females still in a fertile period of their lives. Recurring radiation exposure may be especially harmful in this group.

A normal abdominal CT scan gives a radiation exposure of 5.76 * 3.22 mSv (range: 1.13-12.71) in females and 4.37 * 1.66 mSv (range: 1.36-8.07) in males (4). There is, however also a low dose abdominal CT available. A low dose abdominal CT scan reduces this radiation load to <2.5 mSv, which is comparable to two abdominal X-rays. Previous studies have shown that a low dose CT-scan can be used in the assessment of acute non-traumatic abdominal pain in patients without prior bariatric surgery (5, 6). In these studies, conditions were diagnosed that were mainly related to the following organs: the large bowel, the small bowel, biliary tracts, pancreas, kidney or bladder, pelvic collections, abdominal wall, liver and chest. The accuracies of the radiologist in this study were respectively 99% and 100%. Low dose CT scans were especially reliable in patients with a body mass index (BMI) <30 kg/m2. The population for the proposed study is post-BS and often falls into this category.

Abdominal pain in BS patients may be caused by acute life-threatening diagnoses such as internal herniation. Reduction in the number of CT scans performed in BS patients is hard to achieve as the only alternative to CT is abdominal surgery. Instead, effort to try to expose patients to lower dose of radiation would be a good alternative to still be able to diagnose abdominal after BS sufficiently.

Study objective

Primary Objective:
• Compare the diagnostic performance of the low dose abdominal CT scan to the normal dose abdominal CT scan in diagnosing causes of abdominal pain.

Secondary Objectives:
• Compare the diagnostic performance of diagnosing internal herniations on the abdominal low dose CT scan to the normal abdominal CT scan.
• Compare perceived image quality between both CT scans
• Analyze the difference between radiation dose measurements expressed as DLP and CTDIvol

Study design

This study is designed as a single-center observational case-control study and will take place in the Spaarne Gasthuis location Hoofddorp. Cases are people with a history of Roux-en-Y Gastric Bypass who present themselves at the emergency room with complaints of abdominal pain and in whom an abdominal CT scan is indicated to investigate the cause of these abdominal pain complaints. Other bariatric surgeries are not included because only patients with a Roux-en-Y gastric bypass are at risk of developing an internal herniation. Patients will receive standard care through the indicated regular CT scan and will be asked to receive an additional low dose CT scan. The data of the low dose CT scan will be compared with the normal dose CT scans of the same patients at a later time.

Participants will be recruited at the emergency department by the attending physician from the surgery department or the emergency department. Patients with abdominal pain after BS interested in participating in this study will receive additional written information and an informed consent interview will be conducted by one of the clinicians on call of the surgery department or the emergency department. Due to the urgent care setting, informed consent forms will be signed immediately after explanation of the informed consent. The patient will then immediately receive a normal and a low dose CT scan. Participation in this study should cause no delay in the normal diagnostic process.
The normal dose CT scan will be used clinically in the diagnosis of the abdominal pain via normal protocol. For the study both the normal dose and the low dose CT scans will be reviewed at a later moment by two independent abdominal radiologists and scored according to standardized protocol. During the interim and final analysis, the assessments of both CT scans will be compared and analyzed. The time between making the CT scan and the assessment of the two independent radiologists will be three months. Subsequently, in the case of a suspected internal herniation, the scan will also be compared with the outcome of the diagnostic laparoscopy.

Study participation will end three months after making the normal dose and low dose CT scan. This allows for a three months follow up. The duration of the study will be until 120 patients are included. It is expected that this will be achieved within six months.

Study burden and risks

Participants will receive an extra low dose CT scan on top of the already planned normal dose CT scan for abdominal pain. The low dose CT scan imposes a very low risk on radiation-induced cancer. There is no direct benefit for the participants, but in the long term it may be that in the event of a recurrence of abdominal pain they will receive less radiation exposure because they can have a low dose CT scan instead of a normal dose CT scan due to the findings in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age >=18 years
- A history of Roux-en-Y Gastric Bypass
- Abdominal pain complaints for which an abdominal CT scan is indicated
- Written informed consent

Exclusion criteria

- Incapacitated or unwilling to provide informed consent
- Current pregnancy
- Known history of adverse reactions to iodinated contrast media or known history of claustrophobia

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2024
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Generic name:	Computer Tomography
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-04-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL85050.100.23