Reference values for gastric emptying scintigraphy after bariatric surgery

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Define reference values for gastric and oesophageal scintigraphy for post-bariatric surgery patients.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON56655

Source
ToetsingOnline

Brief title
SCATTER

Condition

- Other condition

Synonym
being overweight, obesity

Health condition

obesitas, bariatrische chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: bariatric surgery, gastric emptying, reference values, scintigraphy

Outcome measures

Primary outcome

Primary objectives:

- to define reference values for gastric scintigraphy using an optimised protocol (GE in T1/2 and retention);

- to define reference values for oesophageal scintigraphy using an optimised protocol;

- to describe SPECT/CT images and determine its benefit for anatomical correlation in asymptomatic (reference) and symptomatic population.

Secondary outcome

Secondary objectives:

- to explore the correlation of GE and oesophageal transit, and weight loss results or symptoms, using prospective data from this study and retrospective data from 53 symptomatic patients and similar studies previously (n=15, patients with RYGB) or currently (n = 24, patients with sleeve gastrectomy) performed in our centre, available for comparison.

Study description

Background summary

Oesophageal and gastric scintigraphy evaluates the function of the gastrointestinal system including variables such as oesophageal transit and gastric emptying (GE). Some variables are known to change after bariatric surgery. In patients that have symptoms of pain or nausea after bariatric

surgery, oesophageal and gastric scintigraphy plays an important role in determining the nature of symptoms and is necessary for adequate treatment. However, literature on reference values in the bariatric population are scarce. At this moment, quantitative evaluation of the scintigraphy cannot be performed and conclusions are based on visual interpretation. There is a need for a standardized scintigraphy protocol for the population that underwent bariatric surgery taking into account the changed anatomy and physiology. Then, reference values that describe the oesophageal transit and GE assessed using scintigraphy have to be determined.

Study objective

Define reference values for gastric and oesophageal scintigraphy for post-bariatric surgery patients.

Study design

In this prospective cross-sectional observational study, participants will undergo oesophageal and gastric scintigraphy to define reference values for post-bariatric surgery patients.

Study burden and risks

The radiation dose of scintigraphy is less than 0.3 mSv. The radiation dose of SPECT/CT is about 1.5 mSv. For comparison, the average background radiation in the Netherlands is 2.0 mSv per year and a transatlantic flight is 0.1 mSv. The radiation burden of this investigation is a minor risk.

Participation in this study implies time investment of one hour to two hours, and an extra visit to Rijnstate hospital Arnhem (although we try to plan the study visit in Rijnstate Arnhem on the same day as the medical visit in Rijnstate Elst to minimise time investments). There is no personal benefit for the participants in this study. This study will result in better understanding of GE after bariatric surgery. There are no special reservations for the used measurements in patients with obesity. Following the risk classification of the NFU, there is a negligible risk for participants of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- age between 18 and 65 years;
- a 2 to 3 year postoperative period after bariatric surgery (gastric sleeve or Roux-and-Y bypass as primary surgery);
- an umcomplicated procedure, and without symptoms of pain/nausea/etc;
- normal weight loss (defined as total weight loss [TWL]: 25% < TWL < 35%).

Exclusion criteria

- Pre-existent oesophageal or gastric motility disorder, dysphagia, reflux, (postprandial) abdominal pain, neurological or metabolic conditions that significantly affect oesophageal or gastric motility;
- When using proton pump inhibitors (PPI) or H2-antagonists, the inability to stop using them for 3 days;
- Using opioids;
- Previous oesophago-gastric surgery, other than bariatric surgery;
- Unable to stop smoking for 24h;
- Pregnancy or breast-feeding;
- Patients with a drug or alcohol addiction.

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):	06-08-2024
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	14-03-2024
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	NL85795.091.23