Sleeve Gastrectomy and the Influence of Concomitant Hiatal Hernia Repair

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To define the exact effect of LSG with and without concomitant HH repair on the prevalence of GERD and GERD-related symptoms in obese patients who are intraoperatively diagnosed with a small HH. Furthermore, to examine the effect of LSG on the...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON42404

Source
ToetsingOnline

Brief title
Sleeve Gastrectomy and Concomitant Hiatal Hernia Repair

Condition

- Gastrointestinal therapeutic procedures

Synonym
excess stomach acid, GERD

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: GERD, hiatal hernia, sleeve gastrectomy

Outcome measures

Primary outcome

Primary endpoint is the differences in total esophageal acid exposure between patients (diagnosed with small HH) who underwent either LSG alone or LSG+HHR.

Secondary outcome

Secondary endpoints consist of 1) changes in prevalence and intensity of GERD symptoms, dysphagia symptoms, and quality of life based on validated questionnaires between these two groups, 2) changes in belching, the number of acid and weakly acidic reflux episodes and manometric changes, 3) the effect of LSG on total esophageal acid exposure, weakly acid exposure and manometric changes in patients with no intraoperatively diagnosed HH who underwent LSG alone and (4) changes in anti-reflux medication usage in both groups of patients within the HH-group and patients in the no-HH-group.

Study description

Background summary

Bariatric surgery is considered a safe and effective treatment for (morbid) obesity. Gastroesophageal reflux disease (GERD) is common among obese patients, both before and after bariatric surgery. It is well accepted that Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) leads to a decrease in postoperative GERD. Despite the fact that the laparoscopic sleeve gastrectomy (LSG) is increasingly popular worldwide, and gradually starts to be more frequently performed than LRYGB, it still remains unclear what the exact effect of LSG on the postoperative prevalence of GERD and the development of denovo GERD is. The presence of a (small) hiatal hernia (HH) is believed to be a risk factor for GERD following LSG. However, there is a lack of clear cut guidelines and

clinical trials / prospective studies comparing LSG with and without combined repair of small hiatal hernias, and the effect of both treatments on postoperative GERD symptoms and esophageal acid exposure.

Study objective

To define the exact effect of LSG with and without concomitant HH repair on the prevalence of GERD and GERD-related symptoms in obese patients who are intraoperatively diagnosed with a small HH. Furthermore, to examine the effect of LSG on the postoperative prevalence of GERD and related symptoms in obese patients without a HH.

Study design

Prospective blinded randomized controlled clinical trial comparing LSG alone with LSG+HH repair in obese patients with a small HH.

Intervention

All 80 patients will undergo an additional pre-operative and three and 12 months postoperative combined pH-impedance and high-resolution manometry (HRM) examination in addition to the standard pre-and postoperative care for patients undergoing LSG. Furthermore, all patients will be asked to complete a pre- and postoperative questionnaire at three and 12 months following surgery concerning reflux symptoms, dysphagia, and quality of life. Patients with an intraoperatively diagnosed fingerprint indentation of the diaphragm, a small dimple surrounding the point where the esophagus passes through the diaphragm and known to possible indicate the presence of a HH, and with the HH measuring < 5cm following exploration, are intra-operatively being randomized for either LSG alone or LSG with concomitant HH repair. For those patients randomized for HH repair, dissection and reduction of the hernia sac will be performed followed by posterior crural closure using non-absorbable sutures. Additional anterior sutures are used if deemed necessary.

Study burden and risks

Included patients will undergo a 24 hours combined pH-impedance monitoring and HRM prior to and three months and one year following surgery, next to the standard pre-operative workup for bariatric surgery. Both HRM and 24-hour combined pH-impedance monitoring are safe procedures without any medical risks. The procedure consists of nasal introduction of a flexible catheter into the esophagus. Potential burdens include the gag-reflex during the placement of the catheter for combined pH-impedance monitoring and HRM. Questionnaires focussing on GERD-symptoms, dysphagia and quality of life will be filled in pre-operatively and three and 12 months following surgery, which will take approximately 15 minutes in total. During surgery, the presence of a small HH

(<5 cm) will be assessed, after which the patient will be randomized for either LSG with concomitant HHR or LSG alone. Additional HH repair will take less than 10 minutes and the medical risks consist of bleeding of one of the hiatal pillars and/or postoperative dysphagia.

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

- Age 18-65 years
- Body Mass Index (BMI) of *40 or *35 with significant comorbidity, with an indication for LSG
- Fit for surgery

Exclusion criteria

- Age <18 and >65 years
- No informed consent
- History of GERD, reflux esophagitis or Barrett*s esophagus
- History of, or intraoperatively diagnosed, paraesophageal hernia (type II) or mixed (type III), or hiatal hernia > 5,0 cm
- Previous anti-reflux surgery, HH repair or previous bariatric surgery
- Pregnant
- Severe esophageal motility disorders

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO Date:	22-03-2016
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	NL55381.100.15