GASTROESOPAHGEAL REFLUX DISEASE AFTER N-SLEEVE VERSUS ROUX-EN-Y GASTRIC BYPASS (GINSBY): A RANDOMISED CONTROLLED TRIAL

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The aim of this study is to determine the effectiveness of N-sleeve in terms of a reduction of GERD in morbidly obese patients, compared to LRYGB.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON50924

Source
ToetsingOnline

Brief title
GINSBY

Condition

- Gastrointestinal inflammatory conditions
- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
GERD, heartburn, reflux

Research involving
Human

Sponsors and support

Primary sponsor: Franciscus Ziekenhuis
Source(s) of monetary or material Support: vakgroep (bariatrische) chirurgie

Intervention

Keyword: Bariatric surgery, Gastroesopahgeal reflux disease, N-Sleeve, Roux-and-Y-gastic bypass

Outcome measures

Primary outcome

The primary objective is to compare GERD improvement after N-Sleeve versus

LRYGB, for morbidly obese patients with GERD undergoing primary metabolic

surgery.

Secondary outcome

- GERD improvement after 5 years;

- Technical failure rate of the procedure;

- To compare HrQoL between the groups;

- To compare weight loss between the groups;

- To compare the cumulative PPI use between the groups;

- To compare complications rates in the first 30 days between the groups;

- To compare long-term complications rates between the groups;

- To compare the length of hospital stay between the groups;

- To compare the duration of primary surgery between the groups;

- To assess the effects of the operations on comorbidity (hypertension,

diabetes mellitus, and dyslipidaemia);

- To compare presence and grade of oesophagitis (grade A-D) and/ or Barrett*s

oesophagus 1 year postoperatively between the groups;

- To analyse cost-effectiveness of N-Sleeve treatment vs. conventional LRYGB.

Study description

Background summary

Bariatric surgery is the most effective treatment for long-term weight loss and reducing comorbidities in morbidly obese patients. Since 2014 laparoscopic sleeve gastrectomy (LSG) is the most frequently performed procedure in bariatric surgery worldwide, followed by laparoscopic Roux-en-Y gastric bypass (LRYGB). Unfortunately, 10-32% of patients develops gastroesophageal reflux disease (GERD) after a LSG, which negatively impacts the Health-related Quality of Life (HrQoL). Moreover, GERD can cause Barrett*s oesophagus, which is a risk factor for the development of oesophageal adenocarcinoma.
Currently, the golden standard surgical technique for morbidly obese patients with GERD is LRYGB. No alternative treatment is available, even though GERD can also develop after LRYGB. Moreover, after a LRYGB patients can develop diarrhea and in a few cases they develop a internial herniation which makes this procedure less attractive to some patients. For patients with contraindications or an explicit wish for another operation, an alternative technique has become available. This technique is a combination of the Nissen fundoplication, and LSG, the Nissen-Sleeve (N-Sleeve). It seems to be an effective and save treatment with 70-88% asymptomatic patients and one (4-10%) complication after one year. Reported complication rates are comparable to standard bariatric procedures (8% - 17% after one year). However, N-Sleeve has only been studied in pilot studies and high-quality data comparing N-sleeve with LRYGB are lacking.

Study objective

The aim of this study is to determine the effectiveness of N-sleeve in terms of a reduction of GERD in morbidly obese patients, compared to LRYGB.

Study design

A phase-III randomised controlled trial.

Intervention

Patients will be randomised between N-Sleeve and LRYGB.

Study burden and risks

The investigational treatment is the N-Sleeve. One year after surgery, all patients will undergo a gastroscopy. Potential burden and risk: The procedures take about 15 minutes, with low risk of complications. We will try to combine the gastroscopy with the standard out-patient clinic visits, implying that no extra hospital visit will be required if possible.
Complications of N-sleeve, are comparable to standard bariatric surgery (4-10% vs. 8-17%, respectively). Moreover, in long-term N-Sleeve seems to improve GERD. In addition this alternative technique may reduce length of hospital stay, readmissions, and re-interventions. Therefore we conclude that the risk and burden for the patients are in proportion to the expected benefits of the intervention.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Morbidly obese, suitable for bariatric surgery according to the international guidelines (i.e. BMI >40 without coexisting medical problems or BMI > 35 with one or more severe obesity-related comorbidities, e.g. metabolic disorders, cardio-respiratory disease, severe joint disease, obesity-related severe psychological problems, etc.);
GERD symptoms, according to the Montreal definition such as heartburn, regurgitation and/or chest pain or PPI treatment because of one or more of these symptoms (20);
Age >=18 year;
Good command of the Dutch or English language to complete the questionnaires;
Written informed consent.

Exclusion criteria

Patients with altered mental status prohibiting the understanding and giving of informed consent;
Patients with achalasia;
Patients with malignancy or other abnormalities at gastroscopy making bariatric surgery unsafe;
Patients with a medical history of abdominal surgery;
Super obese (BMI >= 50kg/m2) ;
Crohn*s disease;
Contraindications to receiving general anaesthesia.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-03-2023
Enrollment:	88
Type:	Actual

Ethics review

Approved WMO

Date:	15-09-2021
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	NL77783.100.21