Study protocol: gastroesopahgeal reflux disease after N-sleeve versus Roux-en-Y gastric bypass (GINSBY): a randomised controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27603

Source
NTR

Brief title
GINSBY

Health condition

GERD, morbidly obese

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

GERD improvement at one year

Secondary outcome

- GERD improvement after 5 years between both groups;
- 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

Background: Laparoscopic sleeve gastrectomy (LSG) and Laparoscopic Roux-en-Y gastric bypass (LRYGB) are the most frequently performed procedures in bariatric surgery. Morbidly obese patients with gastroesophageal reflux disease (GERD) are only eligible for LRYGB. For patients with a contraindication for LRYGB or a specific wish for LSG, there is a new procedure the Nissen-Sleeve (N-Sleeve). The aim of this study is to compare GERD improvement at one year after N-Sleeve versus LRYGB.
Method: This is a single centre, phase III, parallel-group randomised controlled non-inferiority trial. Morbidly obese patients older than 18 with GERD according to the Montreal definition are included after obtaining informed consent. Exclusion criteria: achalasia, abnormalities on gastroscopy, super obese (BMI ≥ 50kg/m2), Crohn's disease and medical history of great abdominal surgery. Patients are randomised between N-Sleeve and LRYGB. The primary outcome is recovery of GERD, defined as < 8 points on the gastroesophageal reflux disease questionnaire (GERD-Q). Secondary outcome measures are quality of life, weight loss, PPI use, postoperative complications, effect on comorbidities, presence of grade of oesophagitis (grade A-D) and/ or Barrett's oesophagus, and cost-effectiveness. Follow-up is after 1, 2, 3, 4, and 5 years. After one year al patients undergo a gastroscopy and at every follow-up moment questionnaires are filled in: GERD-Q, RAND-36, BAROS, EQ-5D, iMCQ, and iPCQ.
Ethics and dissemination: The protocol has been approved by the Medical Research Ethics Committees United (MEC-U), Nieuwegein, on 15 September 2021. The trial results will be submitted for publication in a peer-reviewed journal and at conference presentations.

Study objective

The N-sleeve is no worse at curing GERD compared to a LRYGB

Study design

baseline 1 year, 2 years, 3 years 4 years, 5 years

Intervention

N-Sleeve or Roux-en-Y gastric bypass

Contacts

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Eligibility criteria

Inclusion criteria

Morbidly obese patients older than 18 years with GERD according to the Montreal definition, eligible for bariatric surgery.
Good command of the Dutch or English language to complete the questionnaires;

Exclusion criteria

Patients with altered mental status prohibiting the understanding and giving of informed consent;
Patients with achalasia;
Patients with malignancy or other abnormalities (such as low- and high-grade dysplasia) 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:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2022
Enrollment:	88
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	05-10-2021
Application type:	First submission

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
NTR-new	NL9789
Other	MEC-U : R21.040

Study results