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

Gepubliceerd: 05-10-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27603

Bron
NTR

Verkorte titel
GINSBY

Aandoening

GERD, morbidly obese

Ondersteuning

Primaire sponsor: -
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

GERD improvement at one year

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

N-Sleeve or Roux-en-Y gastric bypass

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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;

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2022
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	05-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9789
Ander register	MEC-U : R21.040

Resultaten