

The effect of sleeve gastrectomy on esophageal reflux

Published: 04-05-2010

Last updated: 03-05-2024

The primary objective is to assess the effect of sleeve gastrectomy on esophageal acid exposure. Other objectives are to assess the effect of sleeve gastrectomy on motility parameters as LES pressure and esophageal peristalsis.

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| Ethical review | Approved WMO |
| Status | Recruitment stopped |
| Health condition type | Gastrointestinal motility and defaecation conditions |
| Study type | Observational invasive |

Summary

ID

NL-OMON34995

Source

ToetsingOnline

Brief title

Sleeve gastrectomy and reflux

Condition

- Gastrointestinal motility and defaecation conditions

Synonym

gastroesophageal reflux, heartburn

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: bariatric, functional research, reflux, sleeve gastrectomy

Outcome measures

Primary outcome

- Reflux time / 24 h before and after LSG

Secondary outcome

- LES pressure before and after LSG
- Esophageal peristalsis before and after LSG

Study description

Background summary

Laparoscopic sleeve gastrectomy (LSG) has recently been introduced as a stand-alone, restrictive bariatric surgery for morbidly obese patients. The procedure leads to significant weight reduction. Despite this positive effect, some patients develop dysphagia or gastroesophageal reflux postoperatively. The pathogenesis of these problems is not completely understood. It has been proposed that LSG has an adverse effect on the function of the lower esophageal sphincter (LES) due to gastric resection at the angle of His, predisposing the patient to postoperative reflux symptoms. To date, there are no studies of LES function and esophageal motility before and after LSG in relation to assessment of esophageal acid exposure (as measured with ph-metry).

Study objective

The primary objective is to assess the effect of sleeve gastrectomy on esophageal acid exposure.

Other objectives are to assess the effect of sleeve gastrectomy on motility parameters as LES pressure and esophageal peristalsis.

Study design

In a prospective study before and three months after LSG esophageal function tests will be carried out.

Study burden and risks

Patients will undergo esophageal manometry and 24 pH-metry before and after LSG. The risk associated with these procedures is limited.

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 years
- Body mass index (BMI) >40 kg/m² or BMI>35 kg/m² with obesity related comorbidities
- Positive screening for sleeve gastrectomy

Exclusion criteria

- Binge-eating or associated eating disorder
- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, theophylline, calcium blocking agents, opioids)

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 28-10-2010

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 04-05-2010

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

CCMO

ID

NL31649.060.10