

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal motility and defaecation conditions
<b>Study type</b>	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

### Public

Universitair Medisch Centrum Utrecht

Postbus 85500  
3508 GA Utrecht  
NL

### Scientific

Universitair Medisch Centrum Utrecht

Postbus 85500  
3508 GA Utrecht  
NL

## 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/m<sup>2</sup> or BMI>35 kg/m<sup>2</sup> 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**

<b>Register</b>	<b>ID</b>
CCMO	NL31649.060.10