

# RELATIONSHIPS BETWEEN POSTPRANDIAL SYMPTOMS AND GASTRIC EMPTYING AFTER SLEEVE GASTRECTOMY

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To assess the relationship between postprandial symptoms and gastric emptying rate. The caloric intake and caloric gastric emptying rate in the pathogenesis of postprandial symptoms after sleeve gastrectomy will also be taken into account

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal conditions NEC
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON37405

### Source

ToetsingOnline

### Brief title

Postprandial and reflux symptoms after sleeve gastrectomy

### Condition

- Gastrointestinal conditions NEC

### Synonym

postprandial and reflux symptoms

### 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:** Dyspepsia, Reflux symptoms, Sleeve gastrectomy

## Outcome measures

### Primary outcome

- postprandial symptoms and food intolerance (scored with a validated questionnaire) after sleeve gastrectomy;
- gastric emptying after sleeve gastrectomy;

### Secondary outcome

- caloric emptying rate (cal/min)
- PPI dependence 12 months after sleeve gastrectomy

## Study description

### Background summary

A sleeve gastrectomy as a stand alone procedure is a relatively new but promising bariatric surgical procedure to treat morbidly obese patients. However, the clinical experience is that postprandial symptoms - to be more precise: symptoms of gastroesophageal reflux and dyspepsia - compromise the beneficial effect of this operation in a considerable proportion of these patients.

Earlier studies have shown that gastric emptying is accelerated for liquids and solids in patients after sleeve gastrectomy. It is not known if gastric emptying or caloric emptying rate is changed in the patients with postprandial symptoms as compared to patients without these complaints.

We hypothesize that the caloric emptying rate will be an important factor in the group of patients with postprandial symptoms en may be independent from the reduced caloric intake in explaining the post-surgical weight loss. The relationship between caloric intake and caloric emptying rate was not studied before.

### Study objective

To assess the relationship between postprandial symptoms and gastric emptying rate. The caloric intake and caloric gastric emptying rate in the pathogenesis

of postprandial symptoms after sleeve gastrectomy will also be taken into account

### **Study design**

In patients with and without postprandial symptoms a gastric emptying study with solid and liquid food will be carried out 12 months after the sleeve gastrectomy

### **Study burden and risks**

Patients will undergo a gastric emptying study postoperatively. The scientific benefits of our study outweigh the nuclear radiation burden (0.49 mSv) of this assessment.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)

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Elderly (65 years and older)

## Inclusion criteria

- Age > 18 years
- Patients must be able to adhere to the study visit schedule and protocol requirements
- Patients must be able to give informed consent and the consent must be obtained prior to any study procedures

## Exclusion criteria

- Binge-eating or associated eating disorder
- Active drug or alcohol addiction
- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, prokinetics, theophylline, calcium blocking agents, opioids)
- Endocrine disease influencing gastric emptying (diabetes mellitus, hyper- or hypothyroidism)

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-10-2012

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

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Date: 07-09-2012  
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	NL40305.060.12