

Changes in GERD after gastric banding - relation with esophageal function parameters and other possible predictive factors

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The aim of this study is to identify predictive factors for the outcome of gastro-esophageal reflux disease after gastric banding. Another aim is to identify predictive factors for the development of dysphagia.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON33304

Source

ToetsingOnline

Brief title

Changes in GERD after gastric banding

Condition

- Gastrointestinal motility and defaecation conditions

Synonym

complaints of heartburn and regurgitation, Gastroesophageal reflux disease (GERD)

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: Esophageal function parameters, GERD, Laparoscopic adjustable gastric banding, Predictive factors

Outcome measures

Primary outcome

The outcome of reflux complaints after gastric banding (increase, steady state or decrease)

Outcome parameters:

- esophageal motility (assessed with high resolution manometry)
- reflux characteristics (assessed with pH/impedance monitoring)
- endoscopic findings (assessed with gastroscopy)

Secondary outcome

Esophageal motility: LES pressure, % peristaltic contractions, mean contractile amplitude

pH/impedance monitoring: % reflux/24 h, frequentation reflux episodes, acid or non-acid, gaseous or liquid)

Patient characteristics: decrease BMI, waist circumference

Study description

Background summary

Laparoscopic adjustable gastric banding is now a usual method in the surgery of obesity. Apart from the weight reduction effect even after long-term follow-up, the band can interfere with esophageal function in a negative way, causing

dysmotility and reflux disease, especially in patients with reflux complaints before gastric banding.

In this study subjects with pre-existing reflux complaints will be analyzed with different techniques before and twelve months after gastric banding. It is important to evaluate patients with reflux complaints before band placement, because these subjects are more susceptible for an aggravation of their reflux disease or dysphagia after band placement.

Study objective

The aim of this study is to identify predictive factors for the outcome of gastro-esophageal reflux disease after gastric banding. Another aim is to identify predictive factors for the development of dysphagia.

Study design

In a prospective follow-up study the subject will undergo an assessment of their reflux complaints before gastric banding, using questionnaires, high resolution manometry and pH/impedance monitoring and gastroscopy. Twelve months after band placement gastro-esophageal reflux complaints will be re-evaluated. Dysphagia after gastric banding will be taken into account.

Study burden and risks

Specific for this study project:

On two moments patients were assessed with functional esophageal research. A manometer probe and a thinner pH/impedance probe are introduced nasally. This procedure has a minimal risk of aspiration, vasovagal collapse or nasal bleeding. After 3 hours, the manometric probe is removed, and the patient leaves the hospital with the 24 hour measurement probe. He/she has to count with this probe in his daily activities

Risk other procedures in context of this project:

Laparoscopic gastric band placement is carried out, with the belonging risks of anesthetic procedures and thrombotic events. In obese subjects extra precautionary measures were made.

The patients do also undergo a gastroscopy two times (an endoscopic evaluation is part of standard care in patients willing bariatric surgery)

Contacts

Public

Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland

Scientific

Universitair Medisch Centrum Utrecht

Postbus 85500
3508 GA Utrecht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- BMI > 40 or > 35 kg/m² with obesity related comorbidity
- Reflux complaints (assessed with Reflux Disease Questionnaire)
- Positive screening in Nederlandse Obesitas Kliniek for laparoscopic gastric band placement

Exclusion criteria

- Severely disordered esophageal motility (<20 mmHg mean contraction amplitude in the lower esophagus and less than 50% peristaltic contractions)
- Unability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, theophylline, calcium blocking agents, opioids)
- Endocrine disease causing overweight (hypothyroidism, hypercortisolism)

- Binge-eating disorder or associated eating disorders
- Active drug or alcohol addiction

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Will not start

Enrollment: 50

Type: Anticipated

Ethics review

Not approved

Date: 12-05-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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.

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In other registers

Register	ID
CCMO	NL27746.041.09