

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

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The first aim of this study is to identify factors which predict an improvement of gastroesophageal reflux after gastric banding. The second aim is to assess the effect of gastric banding on gastroesophageal reflux after the operation.

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

Summary

ID

NL-OMON34813

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

- Change in reflux symptoms before and 12 months after gastric banding

Outcome parameter: Reflux disease questionnaire (RDQ) score

Secondary outcome

- Change in esophageal reflux parameters before and 12 months after gastric banding

Outcome parameters:

- esophageal motility (LES pressure, percentage peristaltic contractions)
- refluxtime (percentage of time with pH<4) during 24 hours.
- endoscopic findings
- Development of dysphagia after gastric banding

Outcome parameter: QLQ-OES 24 dysphagia score

Study description

Background summary

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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 will be analyzed who are eligible for gastric band placement. Those with pre-existing reflux complaints will be asked to participate in this study. They will be assessed 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 after band placement.

Study objective

The first aim of this study is to identify factors which predict an improvement of gastroesophageal reflux after gastric banding.

The second aim is to assess the effect of gastric banding on gastroesophageal reflux after the operation.

Study design

In a prospective follow-up study the subjects will undergo an assessment of their reflux disease 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.

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 patients 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

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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 het

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: Basic science

Recruitment

NL

Recruitment status: Will not start

Enrollment: 100

Type: Anticipated

Medical products/devices used

Generic name: esophageal manometry

Registration: Yes - CE intended use

Ethics review

Approved WMO

Date: 08-04-2010

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.

In other registers

Register

CCMO

ID

NL29877.041.09