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 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-OMON33684

Source
ToetsingOnline

Brief title
Changes in GERD after gastric banding

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Gastroesophageal reflux disease, GERD, reflux complaints

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: GERD, Laparoscopic adjustable gastric band, Predictive factors, Preoperative function parameters

Outcome measures

Primary outcome

The identification of predictive factors in the pattern of reflux complaints

and impaired esophageal transit before and after gastric banding, as measured

with manometry and pH/impedance monitoring. Therefore, patients in which reflux

complaints decrease, increase or stay unchanged postoperatively will be

compared with each other.

Secondary outcome

- LES pressure

- % reflux / 24 hours

- Body Mass Index

- Waist Circumference

Study description

Background summary

Laparoscopic adjustable gastric banding is nowadays a usual method in the surgical treatment of obesity. Apart from the weight reduction effect even after long-term follow-up, it can interfere with esophageal function in a negative way, causing dysmotility or 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 after laparoscopic adjustable gastric banding. It is important to evaluate patients with reflux complaints before band placement, because these subjects are susceptible for reflux disease or dysphagia after band placement.

Pathologic findings can be a contraindication for gastric banding.

Study objective

The aim of this study is to identify predictive factors for the outcome of gastro-esophageal 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 subjects will undergo an assessment of their reflux complaints before gastric banding, using gastroscopy, esophageal manometry an pH/impedance monitoring and two validated questionnaires. Twelve months after band placement gastroesophageal reflux complaints will be re-evaluated. Dysfagia after gastric banding will be taken into account.

Study burden and risks

Participation is this study implies visits to the UMC Utrecht. Before and after gastric banding with an interval of at least twelve months, esophageal manometry and pH/impedance monitoring will be carried out in this patients. The risk associated with these procedures is limited.

Preoperatively it's important to identify hiatus hernia and reflux esophagitis. This ailments can be repaired surgically or treated with medication respectively. Hence a gastroscopy is carried out before gastric band placement. Twelve months after band placement a gastroscopy is repeated. It's particularly important to do this, since the number of patients who develop an esophagitis after band placement can not be neglected [Suter et al., Arch Surg 2005].

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 BMI > 35 with comorbidity
- Reflux complaints (RDQ > 0)
- Positive screening in Nederlandse Obesitas Kliniek for laparoscopic gastric band placement

Exclusion criteria

- Severly disordered esophageal motility (< 20 mmHg mean contraction amplitude in the lower esophagus and less than 50% peristaltic contractions)
- 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

Medical products/devices used

Generic name:	manometry
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	17-02-2009
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.

In other registers

Register	ID
CCMO	NL25379.041.09