Factors determining optimal gastric band adjustment

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON33447

Source
ToetsingOnline

Brief title
Determining optimal band adjustment

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
gastric band adjustment

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: adjustment, gastric band, optimal

Outcome measures

Primary outcome

Bolus transit time and esophageal clearance in different adjustment stages of the gastric band, as assessed with high resolution manometry and impedance monitoring.

Secondary outcome

Complaints of dysphagia reported by the patient, measured with a 'visual analog scale'(VAS)-score

Study description

Background summary

Gastric banding is nowadays an effective surgical treatment for obesity. The band reduces the amount of food which can enter the stomach during a certain period and helps the patient in this way to reduce weight. The gastric band can be adjusted at an access port placed just underneath the skin. If the patients* weight increases, the band is inflated and in case of dysphagia or vomiting, the band is deflated. The decision to adjust is made on clinical grounds, based on the doctor*s experience. Hence, there is a large variation in the filling moments in different patients. In this study will be focused on the effect of band adjustment with different volumes on esophageal bolus transit time and clearance, by using high resolution manometry. Simultaneously the pressure in the gastric band is measured. Physiologically more exact adjustment can help to achieve good weight loss and to prevent esophageal problems in the long term.

Study objective

The primary objective of this study is to assess the effect of band placement and of different stages of band adjustment on the esophageal bolus transit time and clearance by using intra-esophageal high resolution manometry and impedance monitoring.

Secondary objectives of this study are:
- to identify the relation between intraband pressure and bolus transit time / esophageal clearance
- to investigate the predictive value of bolus transit measurement and intraband pressure measurement for the optimal restriction of the band, determined by means of a *passage comfort* visual analogue scale.

Study design

In this pilot-study, patients come to the UMC Utrecht before the gastric band placement to assess their esophageal motility pattern preoperatively with high resolution manometry. Six week postoperatively they return to the UMC for the first adjustment of their band. During this assessment intraband pressure will be measured at different filling volumes. At the same time high resolution manometry is carried out to assess the passage of fluid and food. With this device, esophageal impedance can also be monitored. These techniques give very detailed information about the bolus transit time and esophageal clearance.

Study burden and risks

Before the gastric band placement, high resolution manometry is carried out in the UMC. In the normal situation the band is adjusted in the Nederlandse Obesitas Kliniek in Hilversum postoperatively. Participation in the study implies that the patient comes to the UMC Utrecht for band adjustment, as a part of this study. The band is inflated / adjusted via a small access port placed just under the skin. In Hilversum patients have to pay for this treatment. The gastric band of the participants in this study will be adjusted during this assessment for free.

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

- Men and women > 18 years of age
- BMI > 40 or > 35 kg/m2 with obesity related comorbidity
- Participation in the follow up care program of the NOK
- Band of same type (SAGB) placed in same hospital (Vitalys Klinieken Velp)

Exclusion criteria

- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, theophylline, calcium blocking agents, opioids)
- Present esophageal motility disorders

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2010
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	high resolution manometry
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-10-2009
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	NL27848.041.09