The Effect of the EndoBarrier Device: A 3-year follow-up of a randomized clinical trial.

Published: 30-06-2015
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This study will be performed to evaluate the effectiveness of the EndoBarrier device for the treatment of obesity 3 years after surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON41836

Source
ToetsingOnline

Brief title
The EndoBarrier follow-up study

Condition

- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Obesity

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Eigen middelen

Intervention

Keyword: 3 years, EndoBarrier, Follow-up, Obesity

Outcome measures

Primary outcome

The percentage of Excessive weight loss to assess the impact of the EndoBarrier on body weight three years after explantation

Secondary outcome

- To assess the Effectiveness of the EndoBarrier device three years after explantation on lowering risk factors associated with morbid obesity.

- To assess long-term patient satisfaction after the EndoBarrier device.

- To assess long-term quality of life in patients after the EndoBarrier device.

- To assess the concentration of fibroblast growth factor 19 (FGF19), total bile salts and bile salts composition in human plasma samples measured using immunological (ELISA) and enzymatic assays, respectively.

Study description

Background summary

Obesity has become a worldwide phenomenon. An estimated 300 million people worldwide are now affected. The number of persons with obesity in the USA has doubled in 30 years. Many people are not helped by diets, behavioural changes or exercise. Surgical procedures that are performed are stomach resections, gastric banding and bypass procedures. These surgical procedures still have a significant rat of complications. With this fact in mind, the idea of creating a minimally invasive device to treat patients with obesity has rissen. Our previous experience with the EndoBarrier device is showing promising results in safety and effectiveness. However, most patients fail to maintain weight loss 2 years after new surgical procedures. Therefore it is of importance to investigate the long-term effectiveness of EndoBarrier procedure.

Study objective

This study will be performed to evaluate the effectiveness of the EndoBarrier device for the treatment of obesity 3 years after surgery.

Study design

3 year follow-up of a randomized clinical trial

Study burden and risks

Patients burden includes 1 visit to the outpatient clinic where 1 blood sample wil be taken. Patients may develop a hematoma after the blood sampling. No other risks are associated with this study.

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

1) Patients who were previously enrolled in the randomized clinical EndoBarrier procedure trial at the MUMC or the Atrium Medical Centre Heerlen regardless of their excess weight loss
2) Patients who have a follow up of at least 3 years.
3) Signed informed consent

Exclusion criteria

1) Post-EndoBarrier conventional bariatric surgery
2) Patients who were lost to follow-up during the previous conducted Endobarrier clinical trial

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):	29-09-2015
Enrollment:	29
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2015
Application type:	First submission

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL51074.068.14