

Laparoscopic adjustable gastric banding (LAGB) versus open vertical banded gastroplasty (VBG). 5-year follow-up study of a prospective randomized trial: clinical results and quality of life.

Published: 02-05-2007

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This study aims to describe the long-term results of a randomized trial comparing LAGB and VBG with regard to clinical results and quality of life.

Ethical review

Approved WMO

Status

Recruitment stopped

Health condition type

Gastrointestinal conditions NEC

Study type

Observational invasive

Summary

ID

NL-OMON30707

Source

ToetsingOnline

Brief title

LAGB vs VBG: 5-year follow-up results

Condition

- Gastrointestinal conditions NEC
- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym

obesity, overweight

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 5-year, LAGB, randomized, VBG

Outcome measures

Primary outcome

1. medication
2. postoperative complications
3. re-operations
4. comorbidity
5. symptoms and complaints
6. dietary habits
7. blood pressure measurement

Laboratory measurements:

1. hemoglobin, urea, creatinin, ASAT, ALAT
2. albumin, total protein
3. cholesterol, triglycerides, HDL, LDL
4. iron, zinc, vitamin B1, B6, B12, folic acid

Quality of life:

1. Nottingham Health Profile I (NHP-I)

2. Nottingham Health Profile II (NHP-II)
3. Visual Analog Scale (VAS)
3. Sickness Impact Profile (SIP)

Secondary outcome

none

Study description

Background summary

The long-term results of the laparoscopic adjustable gastric banding (LAGB) are not well known. The value of this technique has been studied in randomized trials in comparison with the vertical banded gastroplasty (VBG). However, only short-term results are described and it is well known that in this patient group complications can arise after many years. Moreover, in the literature it appears that after VBG the weight loss is quick but tends to seize after 2 years while after LAGB the weight loss is slowly but more durable.

The positive results after bariatric surgery on the quality of life is well described in literature. However, this has never been done in a prospective and randomized manner.

Study objective

This study aims to describe the long-term results of a randomized trial comparing LAGB and VBG with regard to clinical results and quality of life.

Study design

All 100 patients of the first study (number 98-112.3) will be asked to visit the outpatient department once. Quality of life questionnaires will be sent to the patients beforehand so they can bring these outfilled. During the visit questions will be asked about clinical results, complications and re-operations. Blood pressure will be measured and 10 ml of blood will be drawn with venapunction.

Intervention

none

Study burden and risks

Outpatient department visit of 20 minutes, outfilling of questionnaires (45 minutes) and drawing of 10 ml blood by venapunction.

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

patients with morbid obesity included in study 98-112.3

Exclusion criteria

none

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): 21-05-2007

Enrollment: 100

Type: Actual

Medical products/devices used

Registration: No

Ethics review

Approved WMO

Date: 02-05-2007

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	NL15921.068.07