Creating a laparoscoplc banded sleeve gastrectomy

Published: 16-03-2020
Last updated: 09-11-2024

To investigate the effect of banded sleeve gastrectomy

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48034

Source
ToetsingOnline

Brief title
RING study

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
morbid obesity, overweight

Health condition

morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis
Source(s) of monetary or material Support: Eigen financiering

Intervention

Keyword: Banding, Bariatric surgery, Sleeve gastrectomie, Weight loss

Outcome measures

Primary outcome

Weight loss: Total body weight loss after 3 years

Secondary outcome

Weight loss: Excess weight loss, Excess Body Mass Index loss

Complications and reoperations

Reduction of comorbidities: tyhpe 2 diabetes, hypertension, hypercholesteromie,

jointcomplaints, OSAS

Quality of life: BARS, SF36 and Body Q

Reflux: GERD-HRQL

f- Food tolerance: F1.10 Quality of Alimentation + additional food groups op 3

and 5 jyears postoperatively

Study description

Background summary

Last decennium the sleeve gastrectomy gained popularity as primary procedure. Despite good short term results, a significant number of sleeve patients regain weight after an initial good result. The cause of weight regain is multifactorial. Dilatation of sleeve is often described as the main cause. Placement of ring around the pouch could prevent dilatation and therefore weight regain.

Study objective

To investigate the effect of banded sleeve gastrectomy

Study design

A prospective, multicenter, randomized controlled trial

Intervention

Banded sleeve gastrectomy

Study burden and risks

- More dysfagia
- More reflux complaints
- Removal of the ring

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Age between and 65 years
- BMI > 40 kg/m2
- BMI > 35 kg/m2 with comorbidities of which expect to improve after surgery
- Medical history of overweight for at least 5 years
- Proven failed attempts to lose weight in a conservative way, or initial good result with relapse
- The intention to fully follow the postoperative program

Exclusion criteria

- Mental disorder, psychotic disorder, severe depression and personality disorder
- Never had professional medical guidance with weight loss
- Not able to participate in long-term medical checks
- Alcohol or drug abuse
- Diseases that form a threat on life expectancy on the short term perioperavtively
- Patients who can not taken care for themselfs, or patients who do not have any social network to take this responsibility
- Pregnacy
- BMI > 60 kg/m2 and/or a planned 'two stage' treatment with a SADI procedure
- Bariatric surgery in the medical history
- Patients with a language barrier which can have affect on medical follow-up and treatment
- Patients with a disease not related to morbid obesity, e.g. Cushing or medication related
- Chronic bowel diseases, e.g. M. Crohn, colitis ulcerosa
- Renal impairment (MDRD<30) of hepatic dysfunction (ASAT/ALAT twice the normal value)
- Patients with therapy resistant reflux symptoms, defined as persistant symptoms despite the use of maximum dose proton-pump-inhibitors (pantozol 2dd40mg/omeprazol 2dd40mg)
- Genetic cause of obesity
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Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-07-2020
Enrollment:	211
Type:	Actual

Ethics review

Approved WMO Date:	16-03-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-04-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-07-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70754.091.19