Bandolera trial: The 'Banded' Gastric Bypass

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To research in three groups whether there is a significant difference between RYGB and BRYGB patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Interventional

Summary

ID

NL-OMON44693

Source
ToetsingOnline

Brief title
Bandolera trial

Condition

- Therapeutic procedures and supportive care NEC

Synonym
Obesity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Banded Gastric Bypass, Bariatric surgery, Roux-en-Y Gastric Bypass

Outcome measures

Primary outcome

Percentage Total Body Weight Loss (%TBWL) after three years.

Secondary outcome

a. Percentage Excess Weight Loss (%EWL), and Body Mass Index (BMI)

b. Percentage total body weight regain

c. Reduction of co-morbidities due to morbid obesity

d. Quality of life: SF-36 en BAROS

e. Incidence of dumping syndrome

f. Difference in complication rates

g. Differences between the two devices: all endpoints written above, operating

time and complications, implantation time and the costs.

Study description

Background summary

Morbid Obesity has become a worldwide health problem. Especially the related co-morbidities like type II diabetes mellitus, hypertension and sleep apnea syndrome, artrosis and dyslipidemia lead not only to an increased morbidity but also to an increased mortality. The Roux-en-Y Gastric Bypass (RYGB) has proven itself as an effective treatment for morbid obesity in the long term.
Unfortunately not all patients prosper with a RYGB, while a number of patients seem to regain weight after a few years. Recently published literature shows that adding a small silicone band to the RYGB might lead to increased weight loss and less weight regain in the long term (Banded RYGB or BRYGB). Two types of silicone bands are currently available: the GaPB ring and the Minimizer ring.
This study researches whether placing a silicone band around a primary performed RYGB indeed leads to increased weight loss and less weight regain. Also we want to research whether there is a difference between the two types of silicone bands available.

Study objective

To research in three groups whether there is a significant difference between RYGB and BRYGB patients.

Study design

Randomized controlled, single centre trial. 130 Patients will be randomized in 2 different groups: the standard Roux-en-Y gastric bypass and the banded gastric bypass with minimizer ring.

Intervention

Group 1:The RYGB is created with a vertical pouch using a 40fr gastric tube (volume 30-50ml), an biliopancreatic limb of 75 cm and alimentary limb of 150cm. Group 2: Same procedure as group 1 adding the Minimizer ring.

Study burden and risks

Ring-related disadventages in comparison with the standard Roux-en-Y gastric bypass:
- erosion, migration, infection, stenosis
- dysfagia and reflux

All patients who participate the study will be asked to fill in 2 questionairs before every visit at the outpatient department: BAROS, SF-36 and GERD-HRQL

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

Fried Guidelines for bariatric surgery:;- age between 18-65 year
- BMI >40 kg/m2 without comorbidities
- BMI > 35 and <40 kg/m2 with obesity related comorbidities
- At least 5 years of overweight
- Proved failed conservative treatments for obesity
- Good motivation to follow the postoperative program

Exclusion criteria

- Fried Guidelines for bariatric surgery
- Specific exclusion criteria for this study: previous bariatric surgery, language barrier, genetic disorder which influences medical advice, patients with obesity due to an other disease e.g. Cushing or medication. Chronic bowel disease e.g. M. Crohn or collitis ulcerosa. Renal failure (MDRD<30) or liver function disorder (ASAT/ALAT twice the normal range). Pregnancy. Patients with therapy-resistancy for refluxdisease, despite the use of proton pomp inhibitors (omeprazol 2 times a day 40mg).

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2015
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	02-06-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2017
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	NL51242.091.14

Study results

Date completed:	01-09-2021
Actual enrolment:	130