Banded gastric bypass in super morbid obesity

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21611

Source
Nationaal Trial Register

Brief title
Banded gastric bypass

Health condition

Super morbid obesity

Sponsors and support

Primary sponsor: Bariatric-Solutions GmbH Kaltenbacherstrasse 24 CH 8260 Stein am Rhein Phone: +41 52 741 65 00 Fax: +41 52 741 65 02
Source(s) of monetary or material Support: Sponsor Bariatric-Solutions

Intervention

Outcome measures

Primary outcome

Weight loss and non-response (insufficient weight loss and weight regain) within 5 years after surgery

Secondary outcome

obesity related comorbidities and medications, (band-related) morbidity and mortality, complications and re-operations, patient satisfaction and health-related quality of life

Study description

Background summary

Weight loss outcomes after bariatric surgery are less favorable in super morbidly obese patients (BMI ≥50 kg/m2).
The aim of this study is to investigate the effectiveness of a banded gastric bypass in super morbidly obese patients on weight loss outcomes including primary and secondary non-response.

Study objective

The banded gastric bypass might be a possible therapy to increase weight loss and decrease long term weight regain in the super morbidly obese patients.

Study design

• Weight loss: 1,2,3,4 and 5 years
• Primary non-response (insufficient weight loss): 1.5 years
• Secondary non-response (weight regain after initial successful weight loss): 2,3,4 and 5 years
• Obesity related comorbidities, medications, morbidity, mortality, complication, re-operations: 30 days, 2 and 5 years
• Quality of life: baseline, 1, 3 and 5 years
• Patient satisfaction: 3 and 5 years

Intervention

Laparoscopic banded Roux-en-Y gastric bypass (B-RYGB)
Laparoscopic non-banded Roux-en-Y gastric bypass (NB-RYGB)

Contacts

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Eligibility criteria

Inclusion criteria

• Age 18-65 years
• Preoperative BMI 50 kg/m2 or greater
• Banded Roux-en-Y gastric bypass or non-banded Roux-en-Y gastric bypass performed
• Informed consent and committed to follow-up appointments

Exclusion criteria

• Prior bariatric procedures

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2019
Enrollment:	142
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
N/A

Ethics review

Positive opinion

Date:	15-10-2019
Application type:	First submission

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
NTR-new	NL8093
Other	METC Máxima MC : METC N19.091

Study results

Summary results
N/A