

Effect of a banded extended pouch in aRoux-en-Y gastric bypass

Published: 19-12-2017

Last updated: 07-12-2024

To investigate the effect of a banded-extended RYGB on weightloss and weightregain on the long term.

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

Summary

ID

NL-OMON55482

Source

ToetsingOnline

Brief title

The UPGRADE 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, Extending, Morbid obesity, Roux-en-Y gastric bypass

Outcome measures

Primary outcome

Weightregain after three years

Total body Weight Loss (%TBWL)

Secondary outcome

- Weight reduction; percentage Excess Weight Loss (%EWL) en Excess Body Mass

Index Loss (%EBMIL)

- Complications and reoperations; eg bleeding, wound infections,

intra-abdominal abcess, anastomotic leakage, vitamin deficiencies

- Reduction of comorbidities; type 2 diabetes, hypertension,

hypercholesterolemia, artrosis, Obstructive Sleep Apnoea Syndrome (OSAS)

- Quality of life; BAROS and SF-36, food tolerance

- Length common channel

- Defecation pattern

- Reflux

Study description

Background summary

The Roux-en-Y gastric bypass (RYGB) has proven to be an effective treatment for

morbid obesity by reducing weight and comorbidities. Extending the pouch may improve weightloss without the increase of complications. Some patients regain weight after initiale good weightloss after RYGB. Placing a minimizer around the pouch may prevent this weighregain.

Study objective

To investigate the effect of a banded-extended RYGB on weightloss and weigtregain on the long term.

Study design

A prospective, single center, randomized controlled study

Intervention

The standard RYGB versus extended pouch RYGB vs banded-extended RYGB.

Study burden and risks

Possible disadvantages of the Banded-extended-RYGB compared to the S-RYGB

- Sometimes removal of the band can be nessecary due to erosion or displacement.
- Reflux
- Dysphagia

Contacts

Public

Rijnstate Ziekenhuis

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NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Age between 18 and 60 years
- BMI >40 kg/m² without comorbidities
- BMI >35 and <40 kg/m² with comorbidities of which expect to improve after surgery
- Medical history of overweight for atleast 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 disorders, severe depression and personality disorders
- 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 of perioperative
- Patients who can not take care for themselves, or patient who do not have any social network to take this responsibility
- Pregnancy
- 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 , eg Cushing or medication related
- Chronic bowel diseases; eg M. Crohn or Colitis Collitis
- Renal impairment (MDRD < 30) or hepatic dysfunction (ASAT / ALAT twice the normal values)
- Patients with therapy-resistant reflux symptoms. Defined as persistent symptoms despite the use of maxiaml dosage proton-pump-inhibitors (PPI) (

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):	10-03-2021
Enrollment:	381
Type:	Actual

Ethics review

Approved WMO	
Date:	19-12-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	07-06-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	03-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO	
Date:	19-05-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	22-11-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	01-07-2024
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	NL62168.091.17