

# Creating a laparoscopic banded sleeve gastrectomy

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To investigate the effect of banded sleeve gastrectomy

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Other condition
<b>Study type</b>	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: type 2 diabetes, hypertension, hypercholesterolemia, joint complaints, 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 years 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 dysphagia
- More reflux complaints
- Removal of the ring

## Contacts

### Public

Rijnstate Ziekenhuis

Wagnerlaan 55  
Arnhem 6815 AD  
NL

### Scientific

Rijnstate Ziekenhuis

Wagnerlaan 55  
Arnhem 6815 AD  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

## Inclusion criteria

- Age between and 65 years
- BMI > 40 kg/m<sup>2</sup>
- BMI > 35 kg/m<sup>2</sup> 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 perioperatively
- Patients who can not taken care for themselves, or patients who do not have any social network to take this responsibility
- Pregnancy
- BMI > 60 kg/m<sup>2</sup> 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**

<b>Register</b>	<b>ID</b>
CCMO	NL70754.091.19