

# Gastric bypass banding for post bariatric dumping and post bariatric late hypoglycaemia

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Explore if the MiniMizer has effect on gastric emptying and on patients with symptoms of early dumping or late hypoglycaemia.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON49962

### Source

ToetsingOnline

### Brief title

CARB study

### Condition

- Other condition
- Gastrointestinal therapeutic procedures

### Synonym

Dumping syndrome, late postprandial hypoglycaemia.

### Health condition

Dumping syndroom

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis

**Source(s) of monetary or material Support:** Eigen financiering

## Intervention

**Keyword:** Banding, Bariatric Surgery, Dumping syndrome, Late hypoglycaemia

## Outcome measures

### Primary outcome

Frequency of early dumping; Frequency of late hypoglycaemia.

### Secondary outcome

- Frequency of starting medication
- Complications and reoperations
- Quality of Life; BAROS, SF-36 and BODY-Q
- Reflux and dysphagia; GERD-HRQL.

## Study description

### Background summary

Morbid obesity is a worldwide problem. The Roux-en-Y Gastric Bypass (RYGB) and one anastomosis gastric bypass (OAGB) are an effective treatment for this problem. But 15 - 20% of the patients after a RYGB/ OAGB has dumping related symptoms. A possible explanation is rapid gastric emptying of food which is rich on carbohydrates. To slow the speed of emptying a MiniMizer around the pouch could be a solution.

### Study objective

Explore if the MiniMizer has effect on gastric emptying and on patients with symptoms of early dumping or late hypoglycaemia.

### Study design

Prospective multicentre pilot study

## Intervention

Placement of a MiniMizer around the pouch.

## Study burden and risks

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

## Contacts

### Public

Rijnstate Ziekenhuis

Wagnerlaan 55  
Arnhem 6800TA  
NL

### Scientific

Rijnstate Ziekenhuis

Wagnerlaan 55  
Arnhem 6800TA  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- Age > 18

- RYGB or OAGB in medical history
- Dumping related symptoms
- Failed treatment of dumping symptoms with dietary adjustments.
- The intention to fully follow the postoperative program.

## Exclusion criteria

- Symptoms of early dumping and late hypoglycaemia.
- Pregnancy
- Patiënts with a language barrier which can have effect on medical follow-up and treatment
- Patients with endocrine disorders that may have influence on gastric emptying (such as diabetes, hypo- or hyperthyreoidism)

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 19-12-2022

Enrollment: 36

Type: Actual

## Ethics review

Approved WMO

Date: 12-10-2020

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO  
Date: 13-01-2025  
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	NL73179.091.20