

# Bariatric procedures and changes in gut hormones and gastric passage

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To assess and compare the gastric emptying rate and gut hormone levels between patients one year after standard RYGB (S-RYGB), B-RYGB and EP-RYGB.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Gastrointestinal therapeutic procedures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON44151

### Source

ToetsingOnline

### Brief title

BIP-study

### Condition

- Gastrointestinal therapeutic procedures

### Synonym

Gastric emptying, hormonal changes

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis

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

### Intervention

**Keyword:** Bariatric surgery, Gastric emptying, Incretins, Roux-en-Y gastric bypass

## Outcome measures

### Primary outcome

Gastric emptying rate and gut hormone levels in patients one year after S-RYGB, B-RYGB and EP-RYGB.

### Secondary outcome

Excess weight loss (%EWL)

## Study description

### Background summary

The most performed type of bariatric surgery performed in Europe is the Roux-en-Y gastric bypass (RYGB). It's an effective treatment of morbid obesity, with long-term weight loss and improvement of obesity related comorbidities. The mechanisms that are involved remain not fully understood. After RYGB the stomach volume is decreased and satiety levels often increase probably due to changes in gut hormones. Gastric emptying is often mentioned as mechanism effecting weight loss by its role in the release of these hormones. A fast pouch emptying in patients with poor weight loss after RYGB is found. To improve the short and long term weight loss after RYGB the technique of the operation is modified and studied. Banding of the gastric pouch (B-RYGB) and creating a longer and narrower pouch, an extended pouch RYGB (EP-RYGB) may, following physical laws, delay pouch emptying resulting in more weight loss after surgery. The more gradual emptying may induce a longer period of gut hormone secretion and therefore increase satiety.

### Study objective

To assess and compare the gastric emptying rate and gut hormone levels between patients one year after standard RYGB (S-RYGB), B-RYGB and EP-RYGB.

### Study design

A prospective trial in which gastric emptying rate and gut hormone levels are measured in patients one year after S-RYGB, B-RYGB and EP-RYGB.

### Study burden and risks

Participation in this study implies extra visits to the participating hospital.  
The absorbed effective dose equivalent of radiation falls into the lowest risk category.

## Contacts

### Public

Rijnstate Ziekenhuis

Wagnerlaan 55  
Arnhem 6815AD  
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### Scientific

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NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Age > 18 years
- Patient underwent a standard RYGB (S-RYGB), B-RYGB or EP-RYGB and is a mean responder (clinic mean Excess Weight Loss +/- 10% or mean Total Body Weight Loss +/- 5%).
- Patient is able to adhere to the study visit schedule and protocol requirements
- Patient is able to give informed consent and the consent must be obtained prior to any study procedures
- Patient had a follow-up period of at least one year after S-RYGB, B-RYGB or EP-RYGB without

any complications

## Exclusion criteria

- Binge-eating or associated eating disorder
- Active drug or alcohol addiction
- Pregnancy and when giving breast feeding
- Gluten allergy
- Inability to stop medication that affects the motility of the upper gastrointestinal tract (anti-cholinergic drugs, prokinetics, theophylline, calcium blocking agents, opioids)
- Endocrine disease influencing gastric emptying (diabetes mellitus, hyper- or hypothyroidism)

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 09-10-2018

Enrollment: 15

Type: Actual

## Ethics review

Approved WMO

Date: 02-11-2017

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:	28-08-2019
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	NL62399.091.17