# Gastrointestinal transit and hormone release after bariatric surgery

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The aim of this study is to assess the effects of a sleeve gastrectomy and a Roux-en-Y gastric bypass on satiety, gastrointestinal transit and hormone release.

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Other condition |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON33034

**Source**
ToetsingOnline

**Brief title**
Gastrointestinal transit and hormone release after bariatric surgery

### Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)
- Gastrointestinal therapeutic procedures

**Synonym**
Obesity, overweight

**Health condition**

morbide obesitas

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis
**Source(s) of monetary or material Support:** wetenschapsfonds;gastrostart

## Intervention

**Keyword:** gut hormones, intestinal transit, RYGB, sleeve gastrectomy

## Outcome measures

### Primary outcome

To assess the effect of a sleeve gastrectomy and gastric bypass on satiety,

diabetes and hormone release.

To assess the effect of a sleeve gastrectomy and gastric bypass on gastric

emptying and intestinal transit time.

### Secondary outcome

To assess correlation between hormone release and transit time in both

procedures

# Study description

### Background summary

Obesity is an increasing problem in the Western world. Obese subjects show reduced satiety after food intake compared to lean subjects. Today, bariatric surgery
seems to be the only effective treatment with long term results.

Bariatric surgery induces a change in satiety hormones. After Roux-en-Y gastric bypass GLP-1 and PYY directly increase before weight loss has occurred. Although ghrelin levels may vary in different studies. Sleeve gastrectomy does not bypass the duodenum and yet has shown to have induced massive weight loss. Changes in ghrelin and PYY have been observed only. No studies have investigated the release of GLP-1 and CCK.
Gastric emptying is accelerated after sleeve gastrectomy and Roux-en-Y gastric bypass. It is not known how this is related to the change in hormones.

Intestinal transit has not been investigated after sleeve gastrectomy and only in few studies after Roux-en-Y gastric bypass.

### Study objective

The aim of this study is to assess the effects of a sleeve gastrectomy and a Roux-en-Y gastric bypass on satiety, gastrointestinal transit and hormone release.

### Study design

On three test days, the patient will receive a meal consisting of two slices of white bread and an egg, the yolk of which was doped with 100 mg 13 C octanoid acid, sodium salt in order to measure gastric emptying. To this meal 10 g of lactulose will be added, to enable measurements of small bowel transit time . The first test day will be before the SG or RYGB, the second test day will be 4-6 weeks after surgery, the third test day will be after one year. During admission an oral glucose tolerance test will be performed twice (one before surgery and one on the third day after surgery). This outline was chosen to assess the direct effects and long term effects on satiety, glucose homeostasis, hormone release and transit time.

### Study burden and risks

• fasting from 24:00 in the evening until 8:30 the next morning (before the testday)
• venous blood sampling procedure (via intravenous cannula)

Benefit for patients individually are none.
Benefit for obesity research in general is providing a better insight in obesity and satiety hormones before and after weight loss/surgery possible leading to the development of less invasive treatments and antiobesity drugs.
Benefit for obese patients in genera may be a better preselection of patients who may benefit most of either sleeve gastrectomy or RYGB preventing secundairy surgery due to failure.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Morbidly obese BMI > 35 - 50 (35-40 + comorbidity) who are candidates for bariatric surgery (sleeve gastrectomy or RYGB)

## Exclusion criteria

History of gastrointestinal surgery (other than cholecystectomy or appendectomy), gastrointestinal diseases that either affect transit or satiety.

# Study design

## Design

**Study type:** Observational invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |

| | |
|---|---|
| Primary purpose: | Treatment |

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-08-2009 |
| Enrollment: | 30 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 07-07-2009 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

## 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 | NL27906.060.09 |