

# DIStal gastriC bypass Outcome in Revision SurgEry after roux-en-y gastric bypass

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The aim of this study is to investigate the effect of two distalisation techniques of a gastric bypass in revisional surgery with standardised limb lengths in total weight loss (TWL) and the need for treatment for protein calorie malnutrition (PCM...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment started
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional research previously applied in human subjects

## Summary

### ID

NL-OMON51099

### Source

ToetsingOnline

### Brief title

DISCOURSE

### Condition

- Other condition
- Gastrointestinal therapeutic procedures
- Malabsorption conditions

### Synonym

bariatric surgery Obesity

### Research involving

Human

### Sponsors and support

**Primary sponsor:** St. Antonius Ziekenhuis

**Source(s) of monetary or material Support:** St. Antonius Ziekenhuis

## Intervention

- Surgical procedure

**Keyword:** Conversion, Distal gastric bypass, Failed gastric bypass, Revision

## Explanation

N.a.

## Outcome measures

### Primary outcome

<p>%total weight loss 1 year after treatment and need for treatment of protein<br />calory malnutrition.</p>

### Secondary outcome

<p>weight loss, co-morbidity remission, protein calory malnutrition grading<br />(debilitating defecation patterns, temporary total parenteral nutrition<br />treatment, revision, mortality), morbidity, nutritional deficiencies, quality<br />of life and patient satisfaction.</p>

## Study description

### Background summary

Up to 35% of morbidly obese patients undergoing Roux-en-Y gastric bypass (RYGB) fail to lose sufficient weight or regain excessive weight after initial weight loss. Currently, there is no standardized approach to revisional surgery after failed RYGB. Distalisation of the RYGB limbs (DGB), with shortening of the common channel and extending either the alimentary limb (AL) or biliopancreatic limb (BPL), can be performed as revisional surgery to induce additional weight loss. To date, there is no general consensus as to optimal surgical technique or limb lengths to be used in distalisation of RYGB in both literature as well as clinical practice.

### Study objective

The aim of this study is to investigate the effect of two distalisation techniques of a gastric bypass in revisional surgery with standardised limb

lengths in total weight loss (TWL) and the need for treatment for protein calorie malnutrition (PCM). In this randomised controlled trial DGB with lengthening of the BPL (DGB type I) will be compared to DGB with extended AL (DGB type II) in order to conclude which surgical technique is the optimal therapeutic strategy as revision surgery following Roux-en-Y gastric bypass.

## **Study design**

Randomised controlled trial.

## **Intervention**

A total of 150 participants will be randomised over two treatment groups: group A will undergo DGB type I and group B will undergo DGB type II.

## **Study burden and risks**

Participants will undergo either DGB type I or DGB type II. The treatment and pre- and postoperative care will not differ from the regular DGB revisional treatment for failed RYGB. Therefore, there are no additional risks associated to this treatment.

Additionally, participants will be asked to fill out written questionnaires regarding defecation patterns and QoL preoperatively as well as 3, 12 and 36 months after treatment.

## **Contacts**

### **Scientific**

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### **Public**

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## Trial sites

### Trial sites in the Netherlands

Elisabeth-Tweesteden ziekenhuis	
Target size:	15
Rijnstate Ziekenhuis	
Target size:	20
Catharina-ziekenhuis	
Target size:	15
OLVG	
Target size:	20
St. Antonius Ziekenhuis	
Target size:	20
Medisch Centrum Leeuwarden (MCL)	
Target size:	20
Groene Hart Ziekenhuis	
Target size:	20
Bravis Ziekenhuis	
Target size:	20

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

### Inclusion criteria

- Age 18-65 years;
- BMI  $\geq 40$  kg/m<sup>2</sup> or BMI  $\geq 35$  kg/m<sup>2</sup> with obesity related comorbidity;
- Weight regain or insufficient weight loss (EWL $<50\%$  or TWL $<20\%$ ) following RYGB;
- Multidisciplinary team screening at one of the bariatric centres;
- Informed consent and willing to enter the follow-up program.

## Exclusion criteria

- Failed Roux-en-Y gastric bypass due to anatomic, surgical reasons (gastric pouch dilatation >50 mL, gastro-gastric fistula, gastro-jejunostomy);
- Distalisation of RYGB is technical infeasible (judgment by surgeon);
- Inflammatory bowel disease, celiac disease, irritable bowel syndrome and other causes of chronic diarrhea;
- Severe concomitant disease (such as carcinomas and neurodegenerative disorders);
- Pregnant women;
- Noncompliance in follow-up or unwilling to undergo surgery;
- Inability of reading/understanding and filling out questionnaires.

## Study design

### Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment started
Start date (anticipated):	15-02-2021
Enrollment:	150
Duration:	36 months (per patient)
Type:	Actual

### Medical products/devices used

Product type:	N.a.
Registration:	No

## IPD sharing statement

**Plan to share IPD:** Undecided

### Plan description

N.a.

## Ethics review

Approved WMO

Date: 14-12-2020

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 24-03-2021

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 21-09-2021

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 07-07-2022

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 16-08-2022

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 31-03-2025

Application type: Amendment

Review commission: MEC-U

## 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	NL75322.100.20
Research portal	NL-007926