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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51099

Source
ToetsingOnline

Brief title
DISCOURSE

Condition

- Other condition
- Malabsorption conditions
- Gastrointestinal therapeutic procedures

Synonym
bariatric surgery, Obesity

Health condition

Obesitas, bariatrische chirurgie

Research involving

Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds

Intervention

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

Outcome measures

Primary outcome

%total weight loss 1 year after treatment and need for treatment of protein

calory malnutrition.

Secondary outcome

weight loss, co-morbidity remission, protein calory malnutrition grading

(debilitating defecation patterns, temporary total parenteral nutrition

treatment, revision, mortality), morbidity, nutritional deficiencies, quality

of life and patient satisfaction.

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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age 18-65 years;
• BMI >=40 kg/m2 or BMI >=35 kg/m2 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 type: Interventional
Masking: Single blinded (masking used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-02-2021
Enrollment:	150
Type:	Actual

Medical products/devices used

Registration:	No

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)

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