Extended pouch gastric bypass vs one anastomosis gastric bypass in patients with BMI>=45

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

Summary

ID

NL-OMON57390

Source
ToetsingOnline

Brief title
EXPANT

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym
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: Bariatric Surgery, Extended pouch gastric bypass, Obesity, One anastomosis gastric bypass

Outcome measures

Primary outcome

Percentage total weight loss (%TWL) 1 and 3 years postoperatively.

Secondary outcome

%TWL 6 months, 2 years and 5 years postoperatively, percentage excess weight loss (%EWL) 6 months, 1 year, 2 years, 3 years and 5 years postoperatively, complications short term (bleeding, anastomotic leakage, anastomotic stenosis, wound infection, intra-abdominal abscess, re-intervention, reoperation, readmission, mortality) according to Clavien-Dindo classification, complications long term (vitamin/electrolyte deficiencies, internal herniation, marginal ulceration, revision) according to Clavien-Dindo classification, comorbidity remission, reflux, dumping, quality of life (QoL), intraoperative complications according to Clavien-Dindo classification, intraoperative conversion to sleeve.

Study description

Background summary

The laparoscopic Roux-en-Y gastric bypass (LRYGB) is a successful surgical treatment for patients with morbid obesity that has been performed for more

than 40 years. Two alternative operation techniques that gained more interest over the last several years are the extended pouch gastric bypass (EPGB) and the one anastomosis gastric bypass (OAGB). Literature shows that both techniques seem to be adequate alternatives for the LRYGB and some studies are even advocating that the EPGB improves mid-term weight loss when compared to the LRYGB, potentially driven by a lower occurrence of weight regain. Both the EPGB and the OAGB use an extended gastric pouch, which probably makes it technically easier to create the gastrojejunostomy in patients with a higher BMI, because less traction on the small intestine and the mesentery is needed to reach the level of the pouch. The most important differ-ence between the EPGB and the OAGB is that there is also a jejunojejunostomy created in the EPGB. As of yet, there is no evidence that this second anastomosis created in the EPGB is necessary since both techniques have not been compared one to one in a prospective randomized controlled trial.

Study objective

In this single-blinded randomized controlled trial the investigators aim to compare the OAGB and the EPGB in terms of percentage total weight loss (%TWL) 1 and 3 years postoperatively, postoperative complications and comorbidity remission in patients with a higher BMI (>=45).

Study design

A multicenter single-blinded randomized controlled trial.

Intervention

A total of 104 participants will be randomized over two treatment groups:
- Group A will undergo the EPGB: an extended pouch gastric bypass with two anastomoses, a gastric pouch of 12-15cm, a biliopancreatic limb of 150cm and an alimentary limb of 100cm.
- Group B will undergo the OAGB: an extended pouch gastric bypass with one anastomosis, an extended pouch of 12-15cm and a biliopancreatic limb of 150cm.

Study burden and risks

Both procedures are considered as adequate alternatives for the LRYGB. Therefore, there are no additional risks associated with this treatment. Additionally, participants will be asked to fill out online questionnaires regarding reflux and dumping complaints, quality of life and patient satisfaction of procedure. These questionnaires are considered as low burden.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
Nieuwegein 3435CM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Age 18-65 years;
• BMI >=45 kg/m2;
• Eligible for LRYGB;
• Dedication to guided preoperative program;
• Intention to follow full postoperative program.

Exclusion criteria

• Secondary bariatric procedure;
• Preoperative use of proton pomp inhibitors (PPIs) for gastroesophageal reflux disease (GERD);
• Medical(-related) cause for morbid obesity or fast weight gain (e.g. Cushing

or medication related);
• Inflammatory Bowel Disease (M. Crohn or Colitis Ulcerosa), celiac disease, irritable bowel syndrome and other causes of chronic diarrhea;
• Renal function disorder (MDRD <30) or liver disease;
• Anticipated absence of follow up program;
• Inability of reading/understanding and filling out questionnaires;
• Pregnant women.

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	104
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-04-2025
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
ClinicalTrials.gov	NCT06204939
CCMO	NL87855.100.25