

A study on safety and efficacy comparing 150cm One Anastomosis Gastric Bypass with 150cm BP limb Roux-en-Y Gastric Bypass (Roux-en-WHY?): An open label, multicentre non-inferiority randomized controlled trial

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

Summary

ID

NL-OMON54369

Source

ToetsingOnline

Brief title

Roux-en-WHY?

Condition

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

Synonym

Obesity, overweight

Health condition

obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Flevoziekenhuis

Source(s) of monetary or material Support: Flevoziekenhuis

Intervention

Keyword: Bariatrics, Bypass, Surgery

Outcome measures

Primary outcome

% excess BMI loss at 2 years

Secondary outcome

% Excess BMI loss at 5 years

Operation time (measured in minutes, from incision until closure),

Diabetes remission (measured in HbA1c%, fasting plasma glucose and the need for anti-diabetic medication will be recorded)

Hypertension remission (need for anti-hypertensive medication will be recorded),

Post-operative complications (<30 days) based on the Comprehensive Complication

Index (CCI, Clavien-Dindo grade III-V complications),

Late complications (>30 days; e.g. bowel obstruction, internal herniation or revision surgery),

Dyslipidaemia control (measured by LDL and total cholesterol and the need for

lipid-lowering medication will be recorded),

Diarrhea (measured using the Bristol Stool Chart, in combination with the stool frequency),

Malnutrition (measured by serum albumin),

Mineral and vitamin deficiencies (measured by serum calcium, parathyroid hormone, iron, ferritin, transferrin coefficient, iron saturation, folic acid, vitamin B1, B6, B12, vitamin D),

Anaemia (measured by haemoglobuline),

Pancreatic activity (measured by fecal elastase in the 24h stools),

Dumping syndrome (measured using the Arts Dumping Scale),

Gastro-esophageal reflux (measured using the GERD-Q questionnaire)

Study description

Background summary

Morbid obesity remains a major health care burden all over the world. Multiple treatments for obesity are in use, but bariatric surgery seems to be the most cost-effective procedure(1)(2)(3)(4). A recent study of Wu et al. showed that bariatric surgery was effective in reducing weight, remission of type 2 diabetes and showed improvements on dyslipidaemia(5), furthermore other studies implied a reduction in 10-year cardiovascular disease risk(6)(7).

The IFSO reported that from 2015-2018, sleeve gastrectomy was the most performed bariatric procedure worldwide with 58.6%, followed by Roux-en-Y gastric bypass (RYGB)(31.2%). However, in the Netherlands the most performed bariatric surgery remains the RYGB(8). The mini gastric bypass (MGB) or the one anastomosis gastric bypass (OAGB) gains ground (9)(10). OAGB works in a similar manner as RYGB due to both restriction and malabsorption and complex metabolic effects. Benefits of OAGB in comparison to RYGB are a shorter operating time(11), a possible difficulty reduction and shorter learning curve(12)(13) and overall technically less demanding in rare reversal procedures(14). Also there are signs that weight loss is greater in the OAGB group(11)(15)(16) comparing it to RYGB with substantial different biliopancreatic limb lengths. Finally, with OAGB there is a smaller chance on internal herniation and bowel

obstruction(15).

Despite these advantages controversies remain about the OAGB procedure. One issue is about the risk on malnutrition and nutritional deficiencies, since multiple studies found adverse events in the form of nutritional complications(11)(17), especially when the biliopancreatic limb (BPL) is 200cm or longer(17). The severity of these nutritional complications -such as excessive weight loss, vitamin deficiency and anaemia- depends on the length of the BPL: a longer BPL induces a higher chance on nutritional complications(17)(18)(19).

Another big worry is about biliary reflux and the chance on developing gastro-oesophageal cancer(20)(21). It has been shown in an experiment with obese rats who have undergone an OAGB that biliary reflux was present. When biopsies were taken from their gastric cardias, a significant increase of eosinophilic polynuclear cell infiltration was found in comparison to the sham rats(22). Nevertheless, no metaplasia, dysplasia or cancer has been observed. Recently a multicentre RCT (YOMEGA) was set up by Robert et al. to compare OAGB with RYGB. 234 patients were assigned (1:1) either to the OAGB group or to the RYGB group. Lengths of the limbs were set on a 200cm BPL for the OAGB group and a 50cm BPL and a 150cm Roux-limb in the RYGB group. The study confirmed non-inferiority of OAGB considering percentage excess BMI loss (%EBMIL) after two years. The YOMEGA trial reported 66 serious adverse events associated with surgery (24 in the RYGB group vs. 42 in the OAGB group; $p=0.042$), of which nine (21.4%) in the OAGB group were nutritional complications versus none in the RYGB group ($p=0.0034$).

In 2017 already, K. Mahawar advised against the length of BPL in OAGB to be >150cm, because of the chance on serious malnutrition(23), later-on findings confirmed similar weight loss in OAGB with a BPL of 150cm vs. 200 cm, without extra risk of malnutrition (24).

Because of the combination of all the results mentioned above, a non-inferiority randomized controlled trial will be performed, comparing an OAGB consisting of a 150cm BPL length with an RYGB consisting of a 150cm BPL length and a 50-75cm Roux-limb: comparing apples with apples.

Study objective

The objective of this study is to find out whether a 150cm BPL-length OAGB is just as good in treating morbidly obese adults when compared to a 150cm BPL-length RYGB with a 75cm Roux-limb in terms of percentage excess BMI loss and nutritional adverse effects after two years.

Study design

prospective non-inferiority randomized controlled trial

Intervention

OAGB (compared with normal RYGB treatment, 1:1)

Study burden and risks

No higher risk is suspected in comparison to regular treatment (RYGB), except for possible biliary reflux and its possible consequence (revision surgery).

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

Inclusion criteria are BMI >40kg/m², or BMI >35kg/m² with at least one of the following comorbidities: type 2 diabetes, hypertension, dyslipidaemia, obstructive sleep apnoea, or osteoarthritis of the hip or knee; age 18-65

years; positive evaluation by a Bariatric multidisciplinary team (BMDT, consisting of psychologists, dietitians, internists and bariatric surgeons); and written informed consent

Exclusion criteria

Exclusion criteria will be presence of *Helicobacter pylori* resistant to eradication therapy, the presence of chronic diarrhoea, or previous bariatric or extensive abdominal surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-12-2021
Enrollment:	298
Type:	Actual

Ethics review

Approved WMO	
Date:	06-05-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	

Date: 12-10-2021
Application type: Amendment
Review commission: METC Amsterdam UMC

Approved WMO
Date: 13-04-2023
Application type: Amendment
Review commission: MEC Academisch Medisch Centrum (Amsterdam)

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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	NL74137.018.20