

The banded mini gastric bypass trial

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Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON51858

Source

ToetsingOnline

Brief title

RiMini trial

Condition

- Gastrointestinal therapeutic procedures

Synonym

weight-loss surgery

Research involving

Human

Sponsors and support

Primary sponsor: Ziekenhuisgroep Twente

Source(s) of monetary or material Support: ZGT Academie

Intervention

Keyword: banded gastric bypass, bariatric surgery, Morbid obesity, one anastomosis gastric bypass (MGB-OAGB)

Outcome measures

Primary outcome

%TBWL after 5 years

Secondary outcome

- (%EWL)
- Decrease of comorbidities such as diabetes mellitus, hypertension, and hypercholesterolemia
- Improvement of quality of life: SF-36 and OBES-Q questionnaires
- Incidence and severity of dumping syndrome
- Incidence and severity of reflux symptoms: GERD-HRQoL questionnaire
- Incidence and complications due to silicone band

Study description

Background summary

Zie K1

Study objective

The main objective is the %TBWL 5 years after surgery. Secondary objectives include Percentage Excess Weight Loss (%EWL); decrease of comorbidities such as diabetes mellitus (DM), hypertension, and hypercholesterolemia; improvement of quality of life: incidence and severity of dumping syndrome; incidence and severity of reflux symptoms; incidence and complications due to band application.

Study design

A prospective randomized controlled trial

Intervention

One group receives *standard* Omega Loop Gastric Bypass (OLGB) and one group receives banded OLGB (bOLGB), which means adjustment of a MiniMizer Ring around the gastric pouch.

Study burden and risks

Expected advantages of bOLGB versus OLGB:

1. Increase of weight reduction, and due to that decrease of comorbidities and/or mortality due to overweight.
2. Long term decrease of weight regain.
3. Decrease of incidence of dumping.

Possible disadvantages of bOLGB versus OLGB:

1. Band-related complications such as erosion, infection, stenosis, or pouch dilatation.
2. Functional gastro-intestinal complains such as dysphagia and reflux.

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

Patients who are eligible for OLAG surgery will be included for this study according the national guidelines for bariatric surgery.

Exclusion criteria

- Bariatric surgery in the past
- Patients
- Chronical inflammatory diseases
- Kidney- or liver dysfunction
- Pregnancy at the start or during the experiment
- Patients with therapeutic resistance in severe clinical complains of reflux
- Allergie for silicone

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:	Completed
Start date (anticipated):	16-08-2022
Enrollment:	210
Type:	Actual

Medical products/devices used

Generic name: MiniMizer Ring
Registration: Yes - CE intended use

Ethics review

Approved WMO
Date: 13-05-2022
Application type: First submission
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO
Date: 20-06-2024
Application type: Amendment
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO
Date: 24-07-2024
Application type: Amendment
Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO
Date: 11-12-2024
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	NL80550.100.22