Outcomes of Mini-Gastric Bypass with Various Biliopancreatic Limb Lengths

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26318

Source
NTR

Brief title
OMGBBPL

Health condition

Morbid obesity

Sponsors and support

Primary sponsor: Center Obesity North-Netherlands and Medical Center Leeuwarden
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Primary endpoint

The primary objective of this study is to determine the total weight loss (% TWL) at 3 years

Definition: TWL = ([initial weight – attained weight]/ initial weight) x 100

Secondary outcome

Secondary endpoints

- The percentage of total weight loss (%TWL) at 1, 2, 4 and 5 years
- The percentage of excess weight loss (%EWL) at 1, 2, 3, 4 and 5 years
Definition EWL = (initial weight – postoperative weight) / (initial weight – ideal weight)
- The percentage excess BMI loss at 1,2, 3, 4 and 5 years
Definition excess BMI loss = (Δ BMI/ (initial BMI -25)) x 100
- Average BMI and distribution of BMI achieved after 1, 2, 3, 4 and 5 years
- Number of patients with total, partial or no remission of hypertension, defined by the changes in dose of anti-hypertensive medication
- Number of patients with total, partial or no remission of diabetes mellitus type 2, defined by the changes in dose of diabetes medication
- To compare the outcomes of the above parameters in the subgroups with different lengths of the BP-limb
- Number of patients with symptoms of biliary reflux after MGB, defined by treatment with medication (antacids, proton pump inhibitor or sucralfate) or a conversion to RYGB due biliary reflux
- Identify specific predictors for the outcomes of the MGB (co-morbitities, body length as surrogate for total small bowel length)

Study description

Background summary

Bariatric surgery is the most effective therapy for obesity, leading to a sustained weight loss, remission of co-morbidities, and a decreased mortality. In 1997 Rutledge introduced the mini-gastric bypass (MGB). This entails a gastrojejunal anastomosis between a long gastric pouch and a jejunal omega loop. Previous studies demonstrated the MGB to be a safe procedure with low mortality and morbidity. The limiting step to broaden the utilization of MGB, is the lack of standardization. Currently, there is no standard guideline for the optimal biliopancreatic (BP) limb length. Technical variations limit the comparability of the currently literature and therefore hinder the obtaining of a consensus on the best way to determine the BP-limb length.
This is a single center retrospective cohort study. From January 2015 to December 2016, all patients who underwent a mini-gastric bypass at the Center Obesity North-Netherlands were included in a prospective database and will be retrospectively analyzed. The follow-up information will be included up to 5 years after the initial surgery. The aim of this study is to describe the MGB procedure as performed in our center and to assess both efficacy and safety of this technique. Furthermore, the aim is to investigate the impact of various BP-limb lengths in terms of weight loss and resolution of co-morbidities.

Study objective

The purpose of the study is to evaluate the outcomes and midterm follow-up in the mini-gastric bypass in terms of weight loss, resolution of co-morbidities and the impact of different BP-limb lengths.

Study design

Day of the surgery and follow-up visit 1 (10-14 months), 2 (18-30 months), 3 (30-42 months), 4 (42-54 months) and 5 (54-66 months) years after surgery.

Intervention

None

Contacts

Public
Medisch Centrum Leeuwarden
Nienke Slagter

0582863859
Scientific
Medisch Centrum Leeuwarden
Nienke Slagter

0582863859

Eligibility criteria

Inclusion criteria

Inclusion criteria
- Treatment at the Center Obesity North-Netherlands
- Mini-gastric bypass between January 2015 and December 2016
- According the international IFSO guidelines:
o BMI ≥ 40 kg/m² or
o BMI ≥ 35 kg/m² with obesity-associated disease: diabetes mellitus type 2, sleep apnea, hypertension, arthrosis, cardiovascular disease, or asthma/COPD.
- Age between 18 and 65 years

Exclusion criteria

Exclusion criteria
- Previous bariatric procedures (band or gastric sleeve)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2020
Enrollment:	737
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8704
Other	RTPO Leeuwarden approved as non-WMO study : RTPO 2020 0036

Study results