

Outcomes of Mini-Gastric Bypass with Various Biliopancreatic Limb Lengths

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26318

Bron

NTR

Verkorte titel

OMGBBPL

Aandoening

Morbid obesity

Ondersteuning

Primaire sponsor: Center Obesity North-Netherlands and Medical Center Leeuwarden

Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary endpoint

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

Definition: $TWL = ([\text{initial weight} - \text{attained weight}] / \text{initial weight}) \times 100$

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

Medisch Centrum Leeuwarden
Nienke Slagter

0582863859

Wetenschappelijk

Medisch Centrum Leeuwarden
Nienke Slagter

0582863859

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria

- Previous bariatric procedures (band or gastric sleeve)

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel: Anders
Toewijzing: N.v.t. / één studie arm
Controle: N.v.t. / onbekend

Deelname

Nederland
Status: Werving gestopt
(Verwachte) startdatum: 03-06-2020
Aantal proefpersonen: 737
Type: Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Niet van toepassing
Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
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NTR-new	NL8704
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Ander register RTPO Leeuwarden approved as non-WMO study : RTPO 2020 0036

Resultaten