LAPAROSCOPIC GASTRIC BYPASS: Common Channel trial

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A randomized controlled trial investigating the optimal common channel length in laparoscopic gastric bypass for morbid obese patients: Distal versus Standard Laparoscopic Roux-en-Y Gastric Bypass.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24253

Bron
NTR

Verkorte titel
DUCATI

Aandoening

Morbid Obesity, Bariatric Surgery
Morbide Obesitas, Bariatrische chirurgie

Ondersteuning

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Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint is sustainable weight loss, which is expressed by the percentage Excess Weight Loss (%EWL) after a follow-up period of 1 year.
Excess weight (kg) will be calculated with the formula EW = AW-IW (actual weight- ideal weight), IW=22 x L2 (L=length in meters). The amount of weight loss will be expressed as percentage excess weight loss (%EWL), and calculated with the formula %EWL = (pre-operative BMI – current BMI) / (pre-operative BMI-25) X 100%.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is designed as a prospective randomized controlled clinical trial comparing two bariatric treatment strategies for morbid obesity. Patients will be randomly allocated 1:1 to A) distal LRYGB or B) standard LRYGB and will be followed for a period of at least 1 year. Randomisation is stratified for participating center. The study will be performed in a clinical and out-patient setting with regular visits at 2,6, and 12 months post intervention.
The study will be set up as a multicenter study with (at least two) bariatric centers of excellence performing at least 500 bariatric procedures annually that have indicated that they are willing to participate pending ethical approval (Lievensberg Ziekenhuis Bergen op Zoom, St. Franciscus Gasthuis Rotterdam).

Doel van het onderzoek

A randomized controlled trial investigating the optimal common channel length in laparoscopic gastric bypass for morbid obese patients:
Distal versus Standard Laparoscopic Roux-en-Y Gastric Bypass.

Onderzoeksopzet

2, 6, and 12 months

Onderzoeksproduct en/of interventie

Distal Laparoscopic Roux-en-Y Gastric Bypass (DLRYGB)
Standard Laparoscopic Roux-en-Y Gastric Bypass (LRYGB)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age 18-60 years
• BMI > 40, or >35 kg/m2 with co-morbidity
• Psychological screening excluding psychiatric and psychological disorders
• Informed consent and willing to enter the follow up program after the operation.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Prior bariatric surgery
• Prior major abdominal surgery (like colonic resection, septic abdomen, aorta surgery, or other procedures with a high risk of intra-abdominal adhesions, which might jeopardise the possibility of performing a DLRYGB, standard LRYGB
• ASA (American Society for Anesthesiologists) classification ≥ IV
• Pregnant women
• Endocrine causes, alcohol or drug abuse

• Severe concomitant disease (carcinomas, neurodegenerative disorders or other disorders presently representing being considered exclusion criteria for bariatric surgery)
• The inability of reading/understanding and filling out questionnaires
• DLRYGB or LYRGB is technically not possible as will be determined by the surgeon during surgery.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	444
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	17-03-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39011
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4313
NTR-old	NTR4466
CCMO	NL43951.101.13
OMON	NL-OMON39011

Resultaten