

Effect of long biliopancreatic limb length in laparoscopic Roux-en-Y Gastric Bypass on weight loss and comorbidities in patients with morbid obesity: a prospective randomized control trial

Published: 13-06-2012

Last updated: 01-05-2024

To investigate the effect of variations in the length of bilipancreatic limb on weightreduction in morbidly obese patients undergoing RYGB-surgery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44795

Source

ToetsingOnline

Brief title

The Elegance trial

Condition

- Other condition
- Gastrointestinal therapeutic procedures

Synonym

morbid obesity, overweight

Health condition

(morbide) obesitas

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: er is geen externe financiering voor deze studie

Intervention

Keyword: Biliopancreatic Limb, Gastric Bypass, Weight Loss

Outcome measures

Primary outcome

Weight reduction; excess weight loss (%EWL).

Secondary outcome

- a. Decrease in comorbidities: diabetes mellitus, hypertension, hypercholesterolemia, artrosis
- b. Quality of life: SF-36 and BAROS
- c. Complicaties and re-operations: bleeding, woundinfections, intra-abdominal abces, anastomosis leakage, vitamine definciencies

Study description

Background summary

Morbid obesity is an increasing medical problem in the western countries. It's related to comorbidities as diabetes mellitus, hypertension, OSAS, artrosis and hypercholesterolemia. The Roux-en-Y Gastric Bypass (RYGB) is an effective surgical therapy for morbidly obese patients. A part of these patients will have disappointing results, and have weight regain on the long term. Some studies show more weight reduction by increasing the biliopancreatic limb in patients with morbid obesity.

Study objective

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To investigate the effect of variations in the length of biliopancreatic limb on weightreduction in morbidly obese patients undergoing RYGB-surgery.

Study design

A prospective, single centre, randomized control trial

Intervention

Standard RYGB with biliopancreatic limb of 50 cm and Roux limb of 175 cm versus Long biliopancreatic limb RYGB with biliopancreatic limb of 150 cm and Roux limb of 50 cm.

Study burden and risks

The study will be a part of the regular medical care. There will be no extra (invasive) research moments for participating patients.

Contacts

Public

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NL

Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patient eligible for bariatric surgery according Fried guidelines;Primary Gastric bypass
- BMI 35 - 40 with a comorbidity
- or BMI > 40;Redo- operation
- medical history: gastric sleeve/ mason / gastric band
- all BMI levels

Exclusion criteria

- Exclusion criteria for bariatric surgery (Fried Guidelines)
- Patients with language problems that intervenes to follow medical advises
- Genetic diseases that intervenes to follow medical advises
- Chronic bowel diseases
- Nephrologic (MDRD <30) or liver diseases (AST/ALT more than twice the norm)
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated):	29-06-2012
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO	
Date:	13-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	17-07-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL40139.091.12

Study results

Date completed:	10-12-2018
Actual enrolment:	280