# LAPAROSCOPIC GASTRIC BYPASS: Common Channel trial

No registrations found.

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|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruitment stopped |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24253

**Source**
NTR

**Brief title**
DUCATI

**Health condition**

Morbid Obesity, Bariatric Surgery
Morbide Obesitas, Bariatrische chirurgie

### Sponsors and support

**Primary sponsor:** G.H.H. Mannaerts, M.D., Ph.D. Gastrointestinal surgeon

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**Source(s) of monetary or material Support:** fund = initiator = sponsor

### Intervention

## Outcome measures

### Primary outcome

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%.

### Secondary outcome

 Operating time, mean hospital stay, intra-operative and post-operative morbidity, and in-hospital mortality. Morbidity is defined as reoperations, reinterventions, re-admissions and serious adverse events. Morbidity is classified as major (anastomotic leakage, major peroperative blood loss due to splenic or vascular hemorrhage, pulmonary embolism, intra-abdominal abscess and intra-abdominal hematoma) or minor (wound infection, urinary tract infection and anastomotic stenosis) complications. Moreover, the rate of extra outpatient and ER visits due to complaints are recorded.
 Improvement in obesity induced co-morbidity (DM-II, hypertension, hypercholesterolemia, OSAS and joint-pain) as defined by Moorehead
 Patient’s health-related quality of life (QoL) objectified by the MOS Short Form 36 (SF 36), Gastro-Intestinal Quality of Life Index, and Obesity related Quality of life the Moorehead-Ardelt II questionnaires and the Bariatric Analysis and Reporting Outcome System (BAROS) score.
 Biochemical and hormonal values following DLRYGB and standard LRYGB. The following parameters will be evaluated: Vitamin B1, B6, B12, D, folic acid, HbA1C, ferritin, iron, transferrin, cholesterol, HDL-cholesterol, LDL-cholesterol, triglyceride.

# Study description

### Background summary

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).

### Study objective

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.

### Study design

2, 6, and 12 months

### Intervention

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

## Contacts

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## Eligibility criteria

### Inclusion criteria

- 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.

### Exclusion criteria

• 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.

## Study design

### Design

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 01-03-2014 |
| Enrollment: | 444 |
| Type: | Actual |

## Ethics review

Positive opinion

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| Date: | 17-03-2014 |

Application type: First submission

# Study registrations

## Followed up by the following (possibly more current) registration

ID: 39011
Bron: ToetsingOnline
Titel:

## Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

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

# Study results