Laparoscopic Gastric Bypass: Common Channel trial

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Objective: The primary objective is to evaluate whether distal LRYGB (DLRYGB) is superior in terms of %EWL after one year follow-up compared to standard LRYGB (LRYGB). Secondary objectives are to evaluate effect on quality-of-life (QOL), cure /...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON39011

Source
ToetsingOnline

Brief title
Common Channel trial

Condition

- Glucose metabolism disorders (incl diabetes mellitus)
- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

Synonym
Morbid Obesity, Overweight

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: geen;gezien geen extra kosten

Intervention

Keyword: bariatric surgery, common channel, gastric bypass, weight loss

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary and-point is %EWL at 1-year

follow-up period

Secondary outcome

Secondary end-points are health related QOL, morbidity/mortality, readmission,

reoperations, re-do surgery.

Study description

Background summary

Rationale: Morbid obesity has become one of the most frequent chronic medical disorders in Western countries, affecting 1.5-2% of the Dutch population. Currently, the laparoscopic Roux-en-Y Gastric Bypass (LRYGB) is considered to be the most effective bariatric treatment option for morbid obesity as it results in adequate weight loss and a significant decrease in comorbidity. Although this technique has been applied for years now, the optimal lengths of the three bowel limbs (alimentary limb (AL), biliopancreatic limb (BL) and common channel (CC)) in order to achieve maximal percentage extra weight loss (%EWL) with minimal side effects such as malabsorption symptoms, are unknown. As `normal` sized bypasses achieve 60% EWL after one year on average (i.e. still 40% body overweight remaining), one could hypothesize that afferent limb lengths should be longer in order to reduce the common channel length, thereby enhancing the %EWL. Such long limb bypasses have been described in retrospective series and small randomized controlled trials (RCT) with improved %EWL results, without increasing malabsorbtion, although these results were only applicable to the selected group of superobese patients. Nevertheless, most of the investigators of these studies suggest that the length of the common channel could be an important parameter for achieving optimal %EWL following LRYGB. The aim of the current study is to investigate the role of the common channel in LRYGB surgery for morbid obesity.
In this RCT distal LRYGB (with 60cm BL and fixed 100cm CC, thus variable AL) will be compared to standard LRYGB, (fixed 150cm AL and 60cm BL, thus variable

CC), in order to define which option is the most effective therapeutic strategy in the morbid obese patient (BMI 40-60 kg/m2) in terms of %EWL after one year.

Study objective

Objective:
The primary objective is to evaluate whether distal LRYGB (DLRYGB) is superior in terms of %EWL after one year follow-up compared to standard LRYGB (LRYGB). Secondary objectives are to evaluate effect on quality-of-life (QOL), cure /improvement of obesity related co-morbidity (i.e. DM-2, hypertension, hypercholesterolemia, Obstructive Sleep Apnoea Syndrome (OSAS)), complications, malnutrition side effects, re-admission rate, and re-operation rate.

Study design

A randomized controlled, open-label, trial comparing bariatric surgery in the morbid obese patient by either DLRYGB with a fixed common channel length of 100cm or standard LRYGB with a variable common channel length.

Intervention

distal LRYGB

Study burden and risks

Distal LRYGB is considered to be a different approach to standard LRYGB but with minimal technical burdens. Potential malnutrition (that may be induced by a short common channel) will be encountered in an early phase by frequent check-up in standardized follow-up visits, which are also routinely performed in standard LRYGB patients. Laboratory tests such as vitamin and iron status are part of the standard follow-up for patients after surgery for morbid obesity. The only difference compared to non participants is that patients have to fill out three QOL-questionnaires on admission and after 12, 36, 60 months. Therefore, the additional burden for participants is considered to be minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

•Age 18-60 years
•BMI > 40, or >35 kg/m2 with co-morbidity
•Conservative therapy - preferably under the guidance of a physician or self help group - has failed or showed only transient results
•Psychological screening excluding psychiatric and psychological disorders
•All patients with 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, which might jeopardise the technical feasibility of LSG or LRYGB)
• BMI > 60 kg/m2
• 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

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:	Recruiting
Start date (anticipated):	24-02-2014
Enrollment:	444
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2013
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24253
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43951.101.13
OMON	NL-OMON24253