The Sleeve versus Bypass trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON25900

Source
Nationaal Trial Register

Condition

- Gastrointestinal therapeutic procedures

Synonym
Morbid obesity

Health condition

morbid obesity / morbiede obesitas bariatric surgery/ bariatrische chirurgie

Research involving
Human

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

- Surigical procedure

Explanation

Outcome measures

Primary outcome

Primary endpoint:

Sustainable weight loss. The amount of weight loss is expressed as percentage excess weight loss (%EWL), and calculated with the formula %EWL = (pre-operative weight ¨C current weight) / (pre-operative weight- ideal weight) X 100%. For this formula a BMI of 25 kg/m2 was taken as the upper limit of normal, i.e. the ideal weight.

Secondary outcome

To evaluate operating time, duration of hospital stay, intra-operative and post-operative in-hospital mortality and morbidity following LSG or LRYGB. Morbidity is defined as re-operations, re-interventions, re-admissions and serious adverse events. Morbidity is also defined as major (anastomotic leakage, major per-operative blood loss due to splenic or vascular haemorrhage, pulmonary embolism, intra-abdominal abscess and intra-abdominal hematoma) or minor (wound infection, urinary tract infection and anastomotic stenosis). Moreover, the rate of extra outpatient and emergency room visits because of complaints following LSG or LRYGB are evaluated.

To evaluate QOL questionnaires are used objectified by the asthma control questionnaire (ACQ), the reflux disease questionnaire (Gerd-Q), the Bariatric Analysis and Reporting Outcome System (BAROS) score, the Gastro-intestinal Quality of life Index (GIQLI), EuroQol-5D (EQ-5D) , Short-form 36 (SF-36) before and following LSG or LRYGB. To evaluate the predictive value of the Sweet eating inventoried by the Dutch Sweet Eating Questionnaire (DSEQ).

To evaluate the need for revision surgery (need to perform an additional bariatric procedure after the performed surgery) as a result of insufficient weight loss or medical complaints within 5 years following the primary bariatric procedure (LSG or LRYGB).

To evaluate the biochemical changes following LRYGB or LSG. In the first year extended blood tests are obtained every 3 months. This is continued in the yearly visits which are common practice in our clinics.

Study description

Background summary

Rationale: Morbid obesity has become one of the most frequent chronic disorders in Western countries, affecting 1.5-2% of the Dutch population. Currently, as the laparoscopic banding procedure is declining in popularity due to its poor percentage Extra Weight Loss (%EWL) results and its high rate of late serious complications, the Laparoscopic Roux-en-Y Gastric Bypass (LRYGB) seems to be one of the best options as a treatment for morbid obesity. However, the higher risk of dumping syndrome makes it a potentially less attractive option due to its negative effects on the quality of life. Laparoscopic Sleeve Gastrectomy (LSG) is a new promising bariatric procedure which has the theoretical advantages of keeping the gastrointestinal tract intact, making it possible to perform endoscopic therapy (gastroscopy, ERCP) after LSG. Because there is no bypass of the jejunum there is theoretically a smaller chance of vitamin deficits and a better QOL. LSG is further an easier and faster procedure. Short term prospective small patient-studies show equal %EWL of both techniques, however long-term results on %EWL of the LSG are not available. The aim of the research proposal, a randomised long-term (5-year FU) comparing LSG with LRYGB, is to clarify this question and analyse the impact on quality-of-life (QOL) of these patient-groups. As certain subgroups (type 2 Diabetes Mellitus (DM-2); BMI >50; sweet eaters; Gastro Esophagal Reflux Disease (GERD)) can have different outcomes compared to those who do not belong to such subgroups, this study explictly takes subgroup analysis into account.

Study objective

"Objective:
The primary objective is to evaluate if %EWL after LSG as bariatric therapy is equal or, within an acceptable margin, inferior to LRYGB.
Secondary objectives are to evaluate QOL, cure /improvement of obesity related co-morbidity (i.e. DM-2, hypertension, hypercholesterolemia, Obstructive Sleep Apnoea Syndrome (OSAS), GERD, weight induced joint pain), complications, readmission rate, re-operation rate, revisive surgery (Re-do) rate, return to work rate. Furthermore, this study evaluates if combining the bariatric procedure with a cholecystectomy in morbidly obese patients with gallbladder stones is to be advocated. Moreover, technical aspects of the LSG and the LRYGB like OR time, blood loss, technical complications and difficulties will be evaluated"

Study design

Study design: A randomized, open label, multicenter non-inferiority trial comparing bariatric treatment of morbid obesity by either LSG or LRYGB.

Intervention

All patients are treated in a fast-track protocol and discharged one day after surgery. Antithrombotic prophylaxes (Fragmin® 5000 u/day) and a fluid diet is continued for two weeks postoperatively. All patients are prescribed proton pump inhibitors for 6 weeks after

surgery.

All participating surgeons are experienced bariatric surgeons that have performed at least 150 LSG and 150 LRYGB and work in bariatric centres of excellence that perform over 500 cases per year.

Laparoscopic Sleeve Gastrectomy or a Laparoscopic Roux en Y Gastric Bypass is performed.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Both treatments in this study are performed on regular basis as a stand-alone therapy for morbid obesity in the Netherlands and abroad, with rising rates of LSG and LRYGB. The place of the LSG as a stand-alone therapy is unknown as long-term results are currently lacking. However, short term results are promising and two short term prospective randomized small-size patient-studies show equal results in terms of %EWL (17,18). The only difference compared to standard LRYGB treatment is that patients have to fill out three QOL-questionnaires on admission and after 3,6,12, 24, 36, 48, 60 months and have to undergo an additional gallbladder ultrasound investigation prior to surgery. The additional burden for study participants is considered to be minimal.

Contacts

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Eligibility criteria

Age
Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

All morbidly obese patients who have been approved for bariatric surgery by the preoperative multidisciplinary team can be included in the sleeve versus bypass trial. Informed consent is mandatory. The criteria for bariatric surgery are age 18-60 years , BMI> 40, or > 35 kg/m2 with obesity-related-comorbidity (such as type 2 diabetes, hypertension, hypercholesterolemia, severe arthrosis and OSAS) for more than 3 years, conservative therapy (preferably under the guidance of a physician or self-help group) that has failed or showed only transient results, completion of psychological screening, excluding patients with psychiatric and psychological disorders, written informed consent and willingness to conclude the lifelong follow up program after surgery.

Exclusion criteria

Exclusion criteria for this study are: diagnosed gastro oesophageal reflux disease (GERD) [16], severe sweet eating [17] prior bariatric surgery, prior major abdominal surgery (such as colonic resection, abdominal sepsis, aortic surgery, which might jeopardise the technical feasibility of LSG or LRYGB) and the inability of reading or understanding the questionnaires.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	620
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	03-07-2012
Application type:	First submission
Review commission:	Medical Research Ethics Committees United (MEC-U) Postbus 2500 3430 EM Nieuwegein 088 320 8784 info@mec-u.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 35688
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4573
NTR-old	NTR4741
CCMO	NL37501.101.11
OMON	NL-OMON35688

Study results

Summary results
none