Laparoscopic Sleeve Gastrectomy versus laparoscopic Roux-en-Y Gastric bypass trial for Morbid Obesity.

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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-...

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

Summary

ID

NL-OMON35688

Source
ToetsingOnline

Brief title
sleeve versus bypass trial

Condition

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

Synonym
morbid obesity, obese weight

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: excess weight loss, gastric bypass, morbid obesity, sleeve gastrectomy

Outcome measures

Primary outcome

Main study parameters/endpoints: The primary and-point is %EWL at 5-years

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 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

Intervention: LSG

Control: LRYGB

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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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 pronounced co-morbidity, for more than 3 years
• 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
• Written informed consent and willing to enter the follow up program after surgery.

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:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-11-2012
Enrollment:	750
Type:	Actual

Ethics review

Approved WMO Date:	03-07-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-01-2014

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 25900
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL37501.101.11
OMON	NL-OMON25900