Onderzoek naar het effect van de SADI vergeleken met de gastric bypass na een eerdere sleeve

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20025

Source
Nationaal Trial Register

Brief title
SAGA-trial

Health condition

SADI, gastric bypass, obesitas, sleeve

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The main objective of this study is to assess the effectivity of RYGB and SADI in terms of amount of additional weight loss in patients after primary sleeve gastrectomy. Weight loss will be assessed in terms of %EWL 2 years after surgery.

Secondary outcome

- To compare the operative time and textbook-outcome (discharge <2 days and no complications per-operative and in the first 30-days).

- To further assess the total additional weight loss at 1 and 2 years after the operation expressed by EWL, TWL and change in BMI

- To evaluate the improvement of obesity-related comorbidities (diabetes mellitus type 2, hypertension, dyslipidemia, sleep apnea and osteo-articular disease). Improvement is considered when use of medication or any medical device is reduced, an improvement is observed in blood results or patients describe a relief of complaints.

- To evaluate any biochemical changes after surgery by means of drawing blood including deficiencies in vitamins and minerals

- To evaluate complaints and/or complications >30 days including dysphagia, gastro-esophageal reflux disease (GERD), defecation problems, , the need for re-do surgery for either weight regain, insufficient weight loss or medical complaints, vitamin deficiencies using the biochemical results, and internal herniation.

- To evaluate the convalescence after surgery (including time to return to work) and the (changes in) quality of life (QoL) after surgery.

- To evaluate the adherence of the included patients to the bariatric program. The adherence is defined as completed visits within time frame of 30 day from standard follow-up program. Additional appointments will be taken into account as well.

- To evaluate any complaints related to dumping syndrome using the Dumping Syndrome Rating Scale

- To evaluate the possible postoperative changes in the gut flora.

Study description

Background summary

Currently, sleeve gastrectomy (SG) is one of the most performed bariatric procedures worldwide. A revision is indicated as a planned secondary procedure after initial super obesity or due to weight regain or insufficient weight loss. This proportion is currently estimated to be up to 20% of all SG’s. The most performed revisional procedure is conversion to Roux-en-Y gastric bypass (RYGB). However, results are disappointing while new procedures are arising with promising results. One of them is the Single Anastomosis Duodenolleal bypass (SADI).

This randomized-controlled trial is used to assess the effectivity of SADI compared with gastric bypass.

The primary endpoint will be the additional weight loss, expressed by percentage of excess weight loss (%EWL) after a follow-up period of 2 years.
Other parameters will be additional and total weight loss expressed by excess or total weight loss (EWL, TWL) and change in body mass index (cBMI), intra- and postoperative complications, gut flora, quality of life, postoperative dumping syndrome complaints, obesity-related comorbidities, recovery after surgery and adherence to the bariatric program.

The burden of participating is to complete the questionnaires during the outpatient clinic visits and to hand in multiple stool samples to evaluate any postoperative gut flora changes. The number of visits, physical examinations, number of blood samples will be the same as any other bariatric patient undergoing a revisional bariatric procedure.

Compared to the conventional revisional procedure, the newer technique used in the intervention group could be associated with a higher risk of vitamin deficiencies and fatty diarrhea.

The expected benefits could be a further increase in weight loss and reduction of obesity-related comorbidities.

Worldwide, an estimated 20.000 patients yearly are faced with the possibility to undergo secondary surgery after primary sleeve gastrectomy. The results of the current study could be taken into account.

Study objective

It is hypothesized that SADI after sleeve gastrectomy for additional weight loss is superior to a gastric bypass as secondary procedure

Study design

Pre-operative screening & 1, 2, 3, 4, 10, 12, 16, 22 and 24 months after surgery

Intervention

Conversion sleeve gastrectomy to SADI

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥ 18 years

- Prior sleeve gastrectomy as primary bariatric procedure.

- Patients must meet the criteria of morbid obesity at least 18 months after the primary sleeve gastrectomy:

• Body mass index (BMI) ≥ 40 kg/m2

• BMI ≥ 35 kg/m2 with persistent obesity-related comorbidities:

 Diabetes Mellitus type 2

 Hypertension

 Hypercholesterolemia

 Sleep apnea

 Osteo-articular disease

• A planned secondary will be regarded as either weight regain or insufficient weight loss, depending on the guidelines described directly above.

- Patient is found eligible for secondary surgery after screening by a dietitian, psychologist, bariatric nurse, and physical therapist and got approval after discussion in an obesity team meeting including a bariatric surgeon.

- Written informed consent is obtained.

Exclusion criteria

- American Society for Anaesthesiologists (ASA) classification ≥ IV

- Severe concomitant disease (e.g. carcinoma, neurodegenerative disorders)

- The inability to read, understand and/or fill out the questionnaires

- Patients with complaints of dysphagia or therapy-resistant gastro-esophageal reflux requiring conversion to RYGB.

- Body mass index < 35 kg/m2 (in the presence of obesity-related comorbidities) or <40 kg/m2 (in the absence of obesity-related comorbidities).

- Disapproval by the psychologist or the dietician to undergo a secondary procedure due to non-compliance to the bariatric program.

- Age < 18

- Incapability to participate due to a language problem, illiteracy or financial problems

- Pregnant or lactating female (Women of child bearing potential must take a pregnancy test prior to surgery)

- History of alcohol or drug abuse (>30 g/day in men or >20 g/day in women)

- Financial issues for daily use of (specific) multivitamin supplements

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL6919
NTR-old	NTR7114
Other	: Volgt

Study results

Summary results
Pending, currently none