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

Gepubliceerd: 29-11-2017 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20025

Bron
Nationaal Trial Register

Verkorte titel
SAGA-trial

Aandoening

SADI, gastric bypass, obesitas, sleeve

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Conversion sleeve gastrectomy to SADI

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2018
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6919
NTR-old	NTR7114
Ander register	: Volgt

Resultaten

Samenvatting resultaten
Pending, currently none