TAiloring LImb length based on total small bowel Length in Omega-loop gastric bypass suRgery : the TAILOR study

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adjusting the length of the biliopancreatic limb in MGB based on total small bowel length will lead to a BMI more within normal range while having less deficiencies of vitamins and minerals and less bowel movements and/or complaints compared to a...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27559

Bron
Nationaal Trial Register

Verkorte titel
TAILOR

Aandoening

class III obesity or class II with co-morbidities e.g diabetes, hypertension, sleep apnea, arthrosis

Ondersteuning

Primaire sponsor: Medisch Center Leeuwarden
Overige ondersteuning: Fit For Me BV wil provide with the multivitamins used by the patients during the study

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percent total weight loss (%TWL) at 5 years.
Assumptions : Control group : TWL of 35% (SD 12%)
Experimental group : TWL of 40% (SD 12 or 9%)
(Absolute difference TWL 5% with possible smaller SD)
Definition : TWL = ([initial weight – attained weight]/ initial weight) * 100

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
One-anastomosis gastric bypass/Mini-GB (OAGB/MGB) surgery aims to reduce weight in obese patients to a healthy BMI. Surgeons usually creat a standard length of the biliopancreatic limb (BP-limb) based on own experience. This practice leads in a substantially percentage of patients to either persisting obesity or underweigth. Furthermore, a substantially percentage of patients develop disturbing diarhea and vitamin and mineral deficiencies. The total small bowel length (TSBL) varies in subjects between less than 5 to more than 10 meters. This variance could have consequenses both for weight loss and for deficiencies after OAGB. The aim of the study is to investigate whether adjusting the length of the BP-limb tot the TSBL leads to more weight loss with smaller variance and to less bowel movements and less deficiencies of vitamins and minerals using an optimal multivitamin Fitforme WSL primo.
Objective:
Primary :
To compare the percent total weight loss (%TWL) at 5 years between the group with the standard BP-length and the group with a adjusted BP-length.
Secondary :
To compare the proportion of patients with 22 <= BMI <= 30 ,the mean number of daily bowel movements and number of days with daily bowel movements > 3 over in the last two weeks before a visit, Quality of life measured by the RAND-36 questionnaire between the groups and the percentage of patients experiencing moderate to severe dumping symptoms defined by the Dumping Severity Score (DSS) between the groups.
To compare the proportion of patients in the two groups who have neither deficiencies of iron, nor vit. D, nor vit B12 without extra suppletion, during the study
Study design: double blind intervention study
Study population:
patients between 18 and 65 years with obesity class III or II with comorbidity scheduled for OAGB surgery and willing to participate.
Intervention :
MGB : patients will be randomly allocated to either a standard BP-limb of 150 cm or to a BP-

limb length based on their TSBL : TSBL < 500 cm : BP-limb : 150 cm ; TSBL 500-700 cm : BP-limb 180 cm ; TSBL > 700 cm : BP-limb : 210 cm.
Main study parameters/endpoints:
Percent total weight loss (%TWL) at 5 years.
Proportion of patients with 22 ≤ BMI ≤ 30 Kg/m2
Mean number of daily bowel movements in the last two weeks
Mean number of days with daily bowel movements > 3 in the last two weeks
Quality of life measured by the RAND-36 questionnaire
Percentage of patients experiencing moderate to severe dumping symptoms defined by the Dumping Severity Score (DSS)
Percentage of patients who have neither deficiencies of iron, nor vit. D, nor vit B12 without extra suppletion

Doel van het onderzoek

adjusting the length of the biliopancreatic limb in MGB based on total small bowel length will lead to a BMI more within normal range while having less deficiencies of vitamins and minerals and less bowel movements and/or complaints compared to a standard BP-limb length

Onderzoeksopzet

End of the study : after 5 years, interim evaluation at year 1,2,3,4

Onderzoeksproduct en/of interventie

Patients will be randomly allocated to one of the two treatment arms :
- 1. A standard BP-limb length of 150 cm
- 2. A BP-limb length depending on total small bowel length (TSBL) measured during the surgical procedure :
- TSBL : < 500 cm : 150 cm
- TSBL : 500-700 cm : 180 cm
- TSBL : > 700 cm : 210 cm

Contactpersonen

Publiek

Medisch Centrum Leeuwarden
Loek de Heide

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Agreed to have mini-gastric bypass surgery
- Age between 18 and 65
- BMI > 40 kg/m2 or
- BMI > 35 kg/m2 with co-morbidity : diabetes, hypertension, OSAS, arthrosis
- Willing to participate with written informed consent before start of the surgery
- A completely measured total small bowel during surgery
- No pre-operative deficiencies of vit B12, vit D and iron, measured with ferritin
- No use of extra (multi-)vitamin supplements with exception of vit D max 800 IU/day
- Able to swallow the multivitamin FFM WLS primo (tested before surgery)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- BMI > 50 Kg/m2
- Known gastro-intestinal disease or history of gastro-intestinal disease, e.g. celiac disease, inflammatory bowel disease
- Known addiction behaviour
- Suspected compliance problems
- Intolerance to Fitforme Primo multivitamin
- Pregnancy planning within the first two years after surgery
- Renal or hepatic insufficiency
- Former abdominal surgery unabling the measurement of the small bowel during laparoscopic surgery
- Parenteral use of vit B12

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	212
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	09-08-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 52591
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7945
CCMO	NL71064.099.19
OMON	NL-OMON52591

Resultaten