TEEN-BEST

Gepubliceerd: 26-07-2018 Laatst bijgewerkt: 19-03-2025

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

Samenvatting

ID

NL-OMON20900

Bron
Nationaal Trial Register

Verkorte titel
TEEN-BEST

Aandoening

Adolescents
Roux-en-Y Gastric Bypass
Sleeve Gastrectomy - Gastric Sleeve
Severe obesity

Ondersteuning

Primaire sponsor: Department of General Surgery, Máxima Medical Center, De Run 4600, 5504 DB Veldhoven,The Netherlands
Overige ondersteuning: Sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

(i) Proportion of adolescents presented to the national board achieving 20% total weight loss (%TWL) 1 year after surgery;
(ii) Incidence of adverse health events and additional surgical intervention.

Toelichting onderzoek

Achtergrond van het onderzoek

Lifestyle interventions are the standard treatment for adolescents with severe obesity. However, only a small subgroup of adolescents with severe obesity are responsive to these lifestyle interventions. Recent literature supports the use of bariatric surgery in unresponsive adolescents. In the Netherlands bariatric surgery in adolescents is only allowed in the context of scientific research.
Therefore, the aim of this multicenter prospective cohort study of adolescents with severe obesity who are undergoing a Roux-en-Y gastric bypass(RYGB) or sleeve gastrectomy(SG) in combination with a multidisciplinary lifestyle intervention is to implement and assess the feasibility, efficacy and safety of this treatment modality in the Netherlands. A historical cohort of adolescents who only received a lifestyle intervention will be compared to the surgical cohort.

Doel van het onderzoek

The overall aim of this study is to implement bariatric surgery including the multidisciplinary care pathway around the procedure for unsuccessfully treated adolescents with severe obesity in the Netherlands. Therefore, feasibility, efficacy and safety of bariatric surgery in adolescents will be assessed. Furthermore, clinical outcomes will be measured and compared with those of a historical cohort of patients participating in a lifestyle intervention program. By assessing feasibility, efficacy and safety we aim to evaluate and optimize the multidisciplinary care pathway for adolescents with severe obesity undergoing bariatric surgery.

Onderzoeksopzet

Primary outcomes:
(i) Proportion of adolescents presented to the national board achieving 20% total weight loss (%TWL) 1 year after surgery;
(ii) Incidence of adverse health events and additional surgical intervention during 5 years follow-up.

Secondary outcomes:
(i) Number of appointments per discipline and follow-up attendance during 5 years follow-up;
(ii) Patient satisfaction at 1, 3 and 5 years after surgery and satisfaction of the multidisciplinary team members after 1, 3 and 5 years from start of the study;
(iii) Perceived organization of care by the multidisciplinary team members after 1, 3 and 5

years from start of the study.

(iv) Change in body weight, change in body mass index (BMI), %TWL and change in BMI standard deviation score during 5 years follow-up;
(v) Prevalence and remission of obesity-related comorbidities during 5 years follow-up;
(vi) Prevalence of cardio metabolic health parameters during 5 years follow-up;
(vii) Bone health measures and incidence of bone fractures during 5 years follow-up;
(viii)Quality of life, psychosocial health measures, and educational attainment at 1, 3 and 5 years after surgery;
(ix) Body composition at 2 and 5 years after surgery.

Onderzoeksproduct en/of interventie

Roux-en-Y gastric bypass (RYGB)
Sleeve Gastrectomy (SG)

Contactpersonen

Publiek

Maxima Medisch Centrum
K.G.H. van de Pas
Ds. Theodor Fliednerstraat 1

Eindhoven 5631 BM
The Netherlands
040-8887372

Wetenschappelijk

Maxima Medisch Centrum
K.G.H. van de Pas
Ds. Theodor Fliednerstraat 1

Eindhoven 5631 BM
The Netherlands
040-8887372

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

(i) Completed a minimum of twelve months in formal lifestyle intervention and/or pharmacotherapy weight loss program;
(ii) Age 13-17 with Tanner stage IV or more;
(iii) Severe obesity meeting IFSO criteria for bariatric surgery, BMI >40 kg/m2 with minor comorbidities or BMI >35 kg/m2 with at least one major comorbidity, corrected for age and sex according to the IOTF criteria;
(iv) Consensus in the multidisciplinary child obesity team, during the multidisciplinary meeting, on a strongly motivated participation of the participant during the lifestyle intervention program so far and in the future (after the bariatric surgery); the participant must have been fully committed to be successful in this program and is expected to continue with this effort after bariatric surgery;
(V) Consensus in the multidisciplinary child obesity team on the diagnosis of non-responding to multidisciplinary lifestyle interventions for now and the near future.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Unable to consent as appropriate;
- Illiteracy (disability to read and understand questionnaires);
- Secondary obesity (obesity caused by a medical condition for example untreated hypothyroidism);
- Known syndrome or genetic disorder (such as Prader-Willi syndrome);
- Skeletal immaturity (Tanner stage < IV, pre-menarche, bone age < 15 years in boys);
- Ongoing addiction (alcohol, drugs, medication);
- Previous bariatric, gastro-esophageal reflux or gastric surgery;
- Uncontrolled psychiatric disorders;
- Inflammatory Bowel Disease (IBD);
- Non-support / non-consent of both parents / caretakers of adolescents aged 13-15 years.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	21-03-2022
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-07-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54829
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7191
NTR-old	NTR7382
CCMO	NL63184.015.17
OMON	NL-OMON54829

Resultaten