TEEN-BEST

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20900

Source
NTR

Brief title
TEEN-BEST

Health condition

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

Sponsors and support

Primary sponsor: Department of General Surgery, Máxima Medical Center, De Run 4600, 5504 DB Veldhoven,The Netherlands
Source(s) of monetary or material Support: Sponsor

Intervention

Outcome measures

Primary outcome

(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.

Secondary outcome

(i) Number of appointments per discipline and follow-up attendance;
(ii) Patient satisfaction and satisfaction of the multidisciplinary team members;
(iii) Perceived organization of care by the multidisciplinary team members.

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

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

(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.

Exclusion criteria

- 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.

Study design

Design

Study type: Interventional

Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-03-2022
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-07-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54829
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results