# Laparoscopic Roux-en-Y Gastric Bypass and Laparoscopic Sleeve Gastrectomy for Severe Obesity in Teenagers: a prospective cohort study.

Published: 05-07-2018
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To implement and assess the feasibility, efficacy and safety of bariatric surgery in adolescents with severe obesity together with a multidisciplinary care pathway around the procedure.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON54829

**Source**
ToetsingOnline

**Brief title**
TEEN-BEST

### Condition

- Other condition
- Appetite and general nutritional disorders
- Gastrointestinal therapeutic procedures

**Synonym**
fattness, Obesity, overweight, severe obesity

**Health condition**

Obesitas

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Maxima Medisch Centrum
**Source(s) of monetary or material Support:** NZA beleidsregel en reguliere zorg

## Intervention

**Keyword:** Adolescents , Roux-en-Y Gastric Bypass, Severe obesity, Sleeve Gastrectomy

## Outcome measures

### Primary outcome

The primary outcome is a composite outcome:

- Proportion of adolescents presented to the national board achieving 20% total

weight loss (%TWL) 1 year after surgery;

- Incidence of adverse health events and additional surgical intervention

during 5 years follow-up.

### Secondary outcome

The secondary outcomes are:

(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.

The secondary endpoints iv, v, vi and viii stated above will be used for this historical cohort as well.

## Study description

**Background summary**

Bariatric surgery is currently the most effective treatment for severe obesity in adults. Recent data also supports the use of bariatric surgery in selected adolescents suffering from severe obesity who don*t show successful weight reduction and remission of comorbidities in the multimodal lifestyle intervention programs. SG and the RYGB have both shown successful weight loss and reduction of obesity related comorbidities in adolescents thus far. In the Netherlands bariatric surgery in adolescents is only allowed in the context of scientific research. Therefore, we propose a prospective cohort study of adolescents with severe obesity undergoing SG or RYGB in combination with a multidisciplinary lifestyle intervention, in order to implement this treatment modality in the Netherlands.
Additionaly, this prospective cohort will be compared with a historical cohort of patients who only received a lifestyle intervention.

## Study objective

To implement and assess the feasibility, efficacy and safety of bariatric surgery in adolescents with severe obesity together with a multidisciplinary care pathway around the procedure.

## Study design

A multicenter prospective cohort study with a sample size of 150 participants. This prospective cohort will be compared with a historical cohort of adolescents who participated in a lifestyle intervention program (COACH - MUMC+).

## Intervention

The adolescents will either receive RYGB or SG, based on the preference of the adolescent and the surgeon. Both procedures will be combined with a lifestyle intervention program. The adolescents with pre-existing reflux complaints or a diaphragmatic hernia will receive a RYGB.

## Study burden and risks

All patients are at risk for the complications associated with a surgery in general, for the complication specific associated with the bariatric procedures (including anastomotic leak, internal herniation, gall stone formation, gastric ulcer, reflux, transient loss of hair, deficiencies of several vitamins and minerals, dyspepsia, dumping syndrome and food intolerance).
Regarding the burden; the participants need to attend the same follow-up visits as adults after bariatric surgery, according to the standard care for adults, combined with the usual care in the lifestyle intervention programs. The same applies for the blood sampling and the ultrasound of the liver. Patients who are included in this study will be asked to fill out multiple questionnaires. The time estimated to fill out these questionnaires is in total 80 minutes. Furthermore, the patients will receive a DEXA scan 3 times during the study. Besides this, a bariatric intervention requires life changing life style adjustments, especially in the way of eating.
The benefits of participating in this study include that untreatable patients receive a bariatric intervention as being an evidence based successful treatment to lose weight and experience remission of comorbidities. Furthermore, other positive effects may occur, such as improvement of quality of life and the mprovement of school performances, as reported in previous studies.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)

## 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;
(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;
- Known syndrome (e.g. Prader-Willi syndrome);
- Skeletal immaturity (Tanner stage <=III) - pre-menarche - bone age < 15 years in boys;
- Ongoing addiction (alcohol, drugs, medication);
- Previous bariatric, gastro-esophageal reflux or gastric surgery;
- Uncontrolled Psychiatric disorders;
- IBD;
- Non-support / consent of both parents / caretakers for children aged 13-15 years.

## Study design

### Design

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|---|---|
| Study type: | Interventional |
| Intervention model: | Other |
| Allocation: | Non-randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Health services research |

### Recruitment

NL

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

# Ethics review

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| Approved WMO Date: | 05-07-2018 |
| Application type: | First submission |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |
| Approved WMO Date: | 01-04-2020 |
| Application type: | Amendment |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |
| Approved WMO Date: | 25-01-2023 |
| Application type: | Amendment |
| Review commission: | METC Maxima Medisch Centrum (Veldhoven) |

# Study registrations

## Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20900
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL63184.015.17 |
| Other | NTR: NTR7191 |
| OMON | NL-OMON20900 |