Bariatric surgery versus conservative treatment in morbidly obese children

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To assess the short term and medium term weight loss after bariatric surgery compared to conservative therapy, to determine the prevalence and the effect of weight loss on obesity associated morbidity in adolescence, to measure the effect of...

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

Summary

ID

NL-OMON47066

Source
ToetsingOnline

Brief title
Bariatric surgery in children (BASIC trial)

Condition

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

Synonym
obesity, overweight

Health condition

morbide obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,ZONMW subsidie gevraagd (voorlopig afgewezen)

Intervention

Keyword: adolescence, children, obesity, surgery

Outcome measures

Primary outcome

Weight loss, excess weight loss, loss excess BMI

Secondary outcome

- Glucose tolerance

- Fat distribution / body composition

- Inflammatory status

- Bloodpressure

- Atherosclerosis and arterial stiffness

- Microvascular function

- Endothelial function

- Myocardial funtion

- Nonalcoholic steatohepatitis

- Quality of life

- Physical activity

- Responsiveness to food

Study description

Background summary

Paediatric obesity is a major problem in the developed world and is the most common disease in children. Obesity is associated with a higher mortality and by serious co-morbidity including type-2 diabetes, dyslipidemia, hypertension, cardiovascular disease, and non-alcoholic steatohepatitis. Obesity is also associated with an impaired quality of life compared to healthy individuals. In children and adolescents the effect of diets and medication is small. Bariatric surgery is the most effective mode of treatment of adult morbid obese patients and has shown similar weight reduction in adolescents.

Study objective

To assess the short term and medium term weight loss after bariatric surgery compared to conservative therapy, to determine the prevalence and the effect of weight loss on obesity associated morbidity in adolescence, to measure the effect of bariatric surgery and weight loss on the quality of life and to estimate the effect of continuous food restriction as result of bariatric surgery on eating behaviour and responsiveness towards food.

Study design

Prospective randomised trial

Intervention

Laparoscopic Adjustable Gastric Banding

Study burden and risks

Surgery of morbid obesity is an accepted method to reduce weight and is also used in adolescents. The patients in the surgery group have a very small risk of death from the operation (until now world wide 0.0%) The chance of complications is 5-10%, which includes wound infection and a slipped gastric band. The latter has to be repositioned with a laparoscopic operation. The expected benefit of the intervention group is large: reduced excess mortality, substantial weight loss, reduction of co-morbidity and an important improvement of the quality of life, with better socio-economic prospects.
The patients in the control group will not benefit directly from the study. They will be offered surgery as soon as the study has proven that reduction of obesity associated morbidity and improved quality of life justify the risk of an operation in adolescents.
The risks and burden of the associated investigations is low.
At assessment the patients get a peripheral venous line to collect 50mL of blood and to collect blood at the oral glucose tolerance test.(part of standard treatment) Ultrasonography of the carotid artery, quality of life and behaviour

tests carry no risks and minimal burden to the patients. DXA . Dopplerultrasonography of the brachial artery and videomicroscopy with 4 minutes ischaemia of the fore arm (done simultaneously) include a short period of discomfort without any risk to the patient. Laser doppler vasomotion is no burden for the patient.
After one year, blood sampling, body composition, the quality of life test and behaviour tests are repeated.
At 3 year the investigations are the same as at initial assessment.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age 14 * 16 years (16 years inclusive)
- Sex and age adjusted BMI > 40 kg/m2 or > 35 kg/m2 with co-morbidity

- > 1 year organized weight reduction reducing attempts with sex and age adjusted weight loss less than 5%
- Written informed consent of the patient and parents
- Demonstrate decisional capacity

Exclusion criteria

- Psychologically not suitable
- Pre menarche
- Bone age < 15 years in boys
- Secondary causes of obesity such as hypothyroidism
- Syndromal causes of obesity such as Prader-Willi syndrome
- Severe cardiorespiratory impairment (ASA class 3 or higher)
- Inability to speak Dutch
- Unwillingness to adhere to follow-up programmes

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2010
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	LAP-BAND AP Adjustable Gastric Banding System

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-07-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-01-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-10-2011
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-02-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01172899
CCMO	NL26279.068.09