Feasibility study adjustable banded gastric bypass.

Published: 29-10-2012
Last updated: 26-04-2024

Testing the feasibility of adjustable gastric banding Roux- and Y gastric bypass in the Atrium Medical Center Parkstad

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON36919

Source
ToetsingOnline

Brief title
Banded bypass

Condition

- Appetite and general nutritional disorders

Synonym
Morbid obesity

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Feasibility study, Gastric banding, Gastric bypass, Primairy surgery

Outcome measures

Primary outcome

Primary: similar or less complication rate of short term complications of a

standard Roux- and Y gastric bypass and similar or less percentages of band

erosion.

Secondary outcome

Secondary: similar or more excess weight loss compared to RYGB.

Study description

Background summary

Patients who are super obese (BMI> 60) not often achieve 50% EWL. Nevertheless patients with a BMI between 35 and 60 not always achieve a 50% EWL. These patients recieve redo surgery after a gastric bypass by placing an adjustable gastric band. By placing an adjustable gastric band during the primary gastric bypass surgery the patient served in 1 operation instead of 2.

Study objective

Testing the feasibility of adjustable gastric banding Roux- and Y gastric bypass in the Atrium Medical Center Parkstad

Study design

Feasibility study

Intervention

Adjustable gastric banding combined with gastric bypass procedure

Study burden and risks

Patients are not exposed to an extra burden by current research. The risks are the risk associated with the surgery they already receive for their diagnosed condition morbid obesity.

Contacts

Public
Atrium Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL
Scientific
Atrium Medisch Centrum

Henri Dunantstraat 5
Heerlen 6419 PC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age 18-65 Years
- BMI * 35 with co-morbidity or BMI * 40
- Signed informed consent
- Approval by the multidisciplinary team

Exclusion criteria

-History of obesity surgery
-History of major abdominal surgery with consecutive malabsorption (no restrictions of the stomach, small and large bowel (exception appendectomy)
-Patients not eligible to implement the adjustable band

- History of/or present alcohol or drug abuse
- History of major psychiatric illness conflicting with the patient compliance
- History of recent or chronic steroid medication
- Autoimmune disease
- Inflammatory bowel disease or malabsorptive disease
- Liver cirrhosis (CHILD B + C)
- Active viral or bacterial disease (HIV, Hepetitis B or C, Tbc etc)
- Pregnancy
- History of cancer in the last 5 years
- Need of long term anticoagulant medication for any reason

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2012
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Adjustable gastric band
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-10-2012

Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Atrium-Orbis-Zuyd

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
CCMO	NL41290.096.12