International, multicentre, open, prospective, randomized study: Banded versus Conventional Laparoscopic Roux-en-Y Gastric Bypass (GABY)

Published: 03-06-2009
Last updated: 30-11-2024

This study will evaluate the effectiveness and safety of the use of the gastric ring in preventing weight increase after 2 years

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

Summary

ID

NL-OMON33374

Source
ToetsingOnline

Brief title
Banded versus conventional Roux-en-Y gastric bypass

Condition

- Other condition

Synonym
high overweight, obesitas

Health condition

obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Clintrio Ltd.
Source(s) of monetary or material Support: Bentec Medical, USA,Industrie

Intervention

Keyword: bypass, gastric, gastric ring, laparoscipic

Outcome measures

Primary outcome

Bodyweight measured as BMI

Secondary outcome

Safety of the gastric ring

Study description

Background summary

Up to now no multicentre comparative study between banded and conventional gastric bypass has been performed.
The GABY study is designed as an international, multicentre, open, prospective, randomized study to compare two methods of bariatric surgery: Banded versus conventional laparoscopic Roux-en-Y gastric bypass.

At least 16 international centres of exellence in bariatric surgery will include at least 384 patients. At least 320 patients must have completed the study after 5 years.

Surgery will be performed according to a standardized operating protocol. The controlgroup will follow the worldwide golden standard of bariatric surgery: gastric bypass. Patients randomized to group B will receive in addition a restrictive silastic ring. The ring is a launched medical product and is registered in the European Community and will be distributed to each centre.

All patients will be treated as under the normal bariatric surgical conditions. No additional risks are expected for those patients receiving the silastic ring.

Study objective

This study will evaluate the effectiveness and safety of the use of the gastric ring in preventing weight increase after 2 years

Study design

Open, randomized

Intervention

Placement of the silastic ring

Study burden and risks

There are no serious side effects known from the silastic gastric ring

Contacts

Public
Clintrio Ltd.

Davenstedter Str. 60
30453 Hannover
DE
Scientific
Clintrio Ltd.

Davenstedter Str. 60
30453 Hannover
DE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Age 18-60
BMI >39-50
Signed informed consent
Volume eater / sweet eater

Exclusion criteria

History of obesity surgery
History of major abdominal surgery

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-09-2009
Enrollment:	24
Type:	Actual

Medical products/devices used

Generic name:	GABP gastric ring
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	03-06-2009
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL27562.096.09