

Laparoscopic adjustable gastric bandings: a prospective randomised study of 400 operations performed with two different devices

Submission date
04/02/2007

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
06/07/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
06/08/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

403-4

Study information

Scientific Title

Acronym

400LAGB

Study objectives

To evaluate eventual differences between the Lap-Band and the Swedish gastric banding for obesity surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No ethics approval required as the interventions involved only well known procedures with widely used devices for the management of obese patients.

Primary study design

Interventional

Study design

Prospective randomised trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Obesity with BMI over 35

Interventions

Lap-Band (Laparoscopic adjustable gastric banding) versus Swedish gastric banding for obesity surgery.

Intervention Type

Device

Phase

Not Specified

Primary outcome(s)

Weight loss and BMI reduction, assessed every six months from surgery.

Key secondary outcome(s)

Complications prevalence and types.

Completion date

12/11/2005

Eligibility**Key inclusion criteria**

All patients were considered eligible for bariatric surgery with:

1. A Body Mass Index (BMI: kg/m^2) greater than 40

2. BMI between 35 and 40 with associated comorbidities
3. Patients with BMI greater than 60 that could not undergo derivative procedures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. BMI greater than 60 (fit for derivative procedures)
2. Previous surgery on the upper abdomen
3. Psychiatric illnesses that could endanger a close postoperative follow-up

Date of first enrolment

12/11/2002

Date of final enrolment

12/11/2005

Locations**Countries of recruitment**

United Kingdom

Italy

Study participating centre

via U.Maddalena 40/a

Ciampino

Italy

00043

Sponsor information**Organisation**

Dolan Park Hospital (UK)

ROR

<https://ror.org/03be8p176>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Dolan Park Hospital (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/10/2007		Yes	No