

# 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

### Contact name

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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.

**Study design**

Prospective randomised trial

**Primary study design**

Interventional

**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:  $\text{kg/m}^2$ ) 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?
<a href="#">Results article</a>	Results	01/10/2007		Yes	No