

# 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

**Registration date**

06/07/2007

**Overall study status**

Completed

**Last Edited**

06/08/2008

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ 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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**Contact details**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure**

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

**Secondary outcome measures**

Complications prevalence and types.

**Overall study start date**

12/11/2002

**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

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

400

**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**

Italy

United Kingdom

**Study participating centre**  
**via U.Maddalena 40/a**  
Ciampino  
Italy  
00043

## **Sponsor information**

### **Organisation**

Dolan Park Hospital (UK)

### **Sponsor details**

Stoney Lane  
Tadderbigge  
Bromsgrove  
Worcestershire  
England  
United Kingdom  
B45 6FN  
mlacey@thehospitalgroup.org

### **Sponsor type**

Hospital/treatment centre

### **ROR**

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

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Dolan Park Hospital (UK)

## **Results and Publications**

### **Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**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