

Laparoscopic adjustable banded gastric plication in morbid obesity

Submission date 21/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/10/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 07/10/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
EMRP22098N

Study information

Scientific Title
Laparoscopic adjustable banded gastric plication in morbid obesity: a prospective study

Study objectives

To evaluate the safety and weight loss effect of laparoscopic adjustable banded gastric plication (LABGAP)

Ethics approval required

Old ethics approval format

Ethics approval(s)

The E-Da Institutional Review Board (IRB) approved on the 11th of May 2009 (ref: EMRP22098N)

Study design

Prospective cohort trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Morbid obesity

Interventions

Gastric banding combined with total greater curvature plication.

This is a single arm trial to evaluate the results and complications associated with the LABGAP.

The total duration of follow up is 2 years.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

1. Weight loss and BMI reduction, assessed every 3 months from surgery
2. Resolution of co-morbidity after surgery

Key secondary outcome(s)

Complication and management of surgery

Completion date

30/06/2012

Eligibility

Key inclusion criteria

1. Body Mass Index (BMI: kg/m²) greater than 40
2. BMI between 35 and 40 with associated comorbidities
3. Age 18-65, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

Key exclusion criteria

1. Substance abuse
2. Psychiatric illnesses that could endanger a close postoperative follow-up
3. History of allergic to silicon materials

Date of first enrolment

01/04/2009

Date of final enrolment

30/06/2012

Locations**Countries of recruitment**

China

Taiwan

Study participating centre

1 Yi-Da Road

Kaohsiung county

Taiwan

824

Sponsor information**Organisation**

E-DA Hospital (Taiwan)

ROR

<https://ror.org/00eh7f421>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

E-Da hospital (Taiwan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration