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Laparoscopic adjustable banded gastric plication in morbid obesity

Submission date 21/09/2010	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 07/10/2010	**Overall study status** Completed	
Last Edited 07/10/2010	**Condition category** Surgery	

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)

Primary study design
Interventional

Study design
Prospective cohort trial

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-mobidity 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/m^2) 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