ISRCTN92780988 https://doi.org/10.1186/ISRCTN92780988

# Single-incision transumbilical laparoscopic Roux-en-Y gastric bypass

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 27/09/2010 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 07/10/2010 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 07/10/2010 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Dr Chih-Kun Huang

**Contact details**
Yi-Da Road
Kaohsiung County
Taiwan
824

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
EMRP17098N

## Study information

**Scientific Title**

Single-incision transumbilical laparoscopic Roux-en-Y gastric bypass: a prospective non-randomised controlled study

## Study objectives
1. To evaluate the feasibility and safety of single-incision transumbilical laparoscopic Roux-en-Y gastric bypass
2.To compare the surgical outcome of the single incision transumbilical and 5-ports laparoscopic Roux-en-Y gastric bypass

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
E-Da Institutional Review Board (IRB) approved on the 13th August 2009 (ref: EMRP17098N)

## Study design
Prospective non-randomised controlled study

## Primary study design
Interventional

## Secondary study design
Non randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Morbid obesity/type II diabetes meliitus

## Interventions
The study prospectively compares single incision transumbilical laparoscopic Roux en Y gastric bypass (intervention arm) and conventional 5-port laparoscopic Roux en Y gastric bypass (control arm). Patients can choose which surgery they prefer for themselves. The total duration for treatment is 2 years and all patients are followed 2 years.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure

Measured peri-operatively and 3 months post-operatively:
1. Operation time
2. Intra-operative complication
3. Post-operative complication
4. Analgesic use
5. Hospitalisation

### Secondary outcome measures
1. Excess weight loss in first year, measured at 1, 3, 6, 9 and 12 months
2. Wound satisfaction, measured at 3 months

### Overall study start date
01/11/2008

### Completion date
31/12/2010

## Eligibility

### Key inclusion criteria
All patients (aged 18 - 65 years, either sex) considered for laparoscopic Roux-en-Y gastric bypass as the treatment method for morbid obesity or Type II Diabetes mellitus

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
100 patients

### Key exclusion criteria
1. Body mass index (BMI) greater than 50
2. Body height greater than 180 cm

### Date of first enrolment
01/11/2008

### Date of final enrolment
31/12/2010

## Locations

### Countries of recruitment
Taiwan

### Study participating centre
**Yi-Da Road**
Kaohsiung County
Taiwan
824

## Sponsor information

### Organisation
E-Da Hospital (Taiwan)

### Sponsor details
1 Yi-Da Road
Kaohsiung County
Taiwan
824

### Sponsor type
Hospital/treatment centre

### Website
http://www.edah-hospital.com

### ROR
https://ror.org/00eh7f421

## Funder(s)

### Funder type
Hospital/treatment centre

### Funder Name
E-Da Hospital (Taiwan)

## 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