

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

Submission date 27/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/10/2010	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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
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

Study type(s)

Treatment

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(s)

Measured peri-operatively and 3 months post-operatively:

1. Operation time
2. Intra-operative complication
3. Post-operative complication
4. Analgesic use
5. Hospitalisation

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

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