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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes