

Trial comparing various methods of liver retraction in Laparoscopic Roux-en-Y Gastric Bypass

Submission date 04/11/2011	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 15/11/2011	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 06/11/2012	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Liver retraction is necessary during Laparoscopic Roux-en-Y gastric Bypass (LRYGB) surgery to make sure that the surgeon has enough space and can see what they are doing. Hypertrophic fatty left lobe of the liver in morbidly obese patients makes liver retraction more challenging for surgeons dealing with weight loss surgery (called bariatric surgeons). Traditional liver retractors require another wound for insertion, are bulky and may cause liver injury. This additional wound may also lead to local wound infection, port site hernia and may add to post-operative pain and discomfort. The response of the liver to the retraction also needs to be addressed. This is the aim of this study which compared three methods: the traditional Nathanson liver retractor (Group I), liver suspension tape (Group II), V shaped liver suspension technique called V-LIST (Group III).

Who can participate?

Patients aged 18-65 years, with a BMI > 32 kg/m² and who have given written informed consent.

What does the study involve?

Participants are randomly allocated to three groups: Nathanson liver retractor (Group I), Liver suspension tape (Group II) and (Group III) on the basis of method of liver retraction used and taken for surgery Laparoscopic Roux-en-Y gastric Bypass (LRYGB).

What are the possible benefits and risks of participating?

The patients in Group II and III may benefit from less liver trauma, fewer trocar wound related complications (a trocar is the device that will be used to provide better access to the abdomen). The patients may need more operative time in Group II and III.

Where is the study run from?

The study will take place at EDa Hospital, Kaohsiung City (Taiwan)

When is the study starting and how long is it expected to run for?

January 2010 to July 2010.

Who is funding the study?
EDa Hospital, Kaohsiung City (Taiwan)

Who is the main contact?
Professor Chih-Kun Huang
dr.ckhuang@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Chih-Kun Huang

Contact details
1 E-Da Road
Jian-Shu Tsuen
Yan-Chau Shiang
Kaohsiung
Taiwan
824

Additional identifiers

Protocol serial number
EMRP30098N

Study information

Scientific Title
A randomised controlled trial comparing various methods of liver retraction in Laparoscopic Roux-en-Y Gastric bypass

Acronym
LRYGB

Study objectives
The patients may benefit from novel retraction techniques like Liver suspension tape, V-shaped liver suspension technique with less trauma to liver and less scarring.

Ethics approval required
Old ethics approval format

Ethics approval(s)
E-Da Hospital Ethics Committee and Institutional Review Board, Taiwan, 15 January 2010 ref: EMRP30098N

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Laparoscopic roux-en-y gastric bypass for obese patients

Interventions

Eligible consenting participants (N=60) will be randomised into 3 groups:

Group I: Nathanson Liver Retractor (n=20)

Group II: Liver Suspension Tape (n=20)

Group III: V-LIST (n=20)

Preoperative liver function test (LFT) (SGOT, SGPT, Total Bilirubin)

Preoperative Liver dimensions measurement

Surgery: We recorded gastric pouch time, operative time, time for liver suspension, Operative view score, Difficulty score, Visual analogue scale (VAS) for pain

LFT (SGOT, SGPT, Total Bilirubin):

Immediate Postop, 18 hours, 1 week and 1 month.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

1. Liver Function Test (LFT) just before surgery immediately post operation and at 18 hours, 1 week and at 1 month after surgery
2. Intra-operative time for gastric pouch, time taken for liver suspension and total operative time

Key secondary outcome(s)

1. Liver dimensions
 2. Difficulty and operative view scores
 3. Visual analogue scale) VAS
- Measured at post operation after day 1 and day 2

Completion date

31/07/2010

Eligibility

Key inclusion criteria

1. Age 18-65 years
2. Body mass index (BMI) > 32 kg/m²
3. Written informed consent

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. Patients younger than 18 or older than 65 years
2. Unresolved psychiatric illness
3. Substance abuse
4. Liver cirrhosis

Date of first enrolment

01/01/2010

Date of final enrolment

31/07/2010

Locations**Countries of recruitment**

Taiwan

Study participating centre

1 E-Da Road

Kaohsiung

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 Kaohsiung (Taiwan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration