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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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
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
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 measure
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

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

Overall study start date
01/01/2010

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
60, 20 in each group

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)

Sponsor details
No.1, Yida Road
Jiaosu Village
Yanchao District
Kaohsiung
Taiwan
82445

Sponsor type
Hospital/treatment centre

Website
http://www.edah-hospital.com/en/index.html

ROR
https://ror.org/00eh7f421

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
E-Da Hospital Kaohsiung (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