

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

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<b>Registration date</b> 15/11/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2012	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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/m<sup>2</sup> 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**  
Prof Chih-Kun Huang

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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

**Study design**

Randomised controlled trial

## Primary study design

Interventional

## 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/m<sup>2</sup>
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