

# Metabolic surgery for body mass index (BMI) < 27 kg/m<sup>2</sup> patients with type 2 diabetes mellitus

<b>Submission date</b> 06/10/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 27/11/2012	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Background and study aims:

Type 2 diabetes mellitus (T2DM) is a disease with high mortality rates. It is the most common endocrine disorder worldwide. People with diabetes are at increased risk of cardiovascular diseases. The current treatment includes diet control, exercise, and use of anti-diabetic medications. However, recent evidence suggests surgery can reduce the symptoms of T2DM, especially in morbidly obese patients. The aim of our study is to evaluate the effectiveness and safety Laparoscopic Roux-en-Y gastric Bypass (LRYGB) surgery in non obese T2DM patients.

Who can participate?

Either male or female patients aged 18 - 65 years, with a Body Mass Index (BMI) of less than 27 kg /m<sup>2</sup>. Participants should also be diagnosed with T2DM for at least 6 months.

What does the study involve?

Laparoscopic Roux-en-Y gastric Bypass (LRYGB) surgery.

What are the possible benefits and risks of participating?

Patients may experience reduced symptoms of T2DM, however there is the risk that there maybe complications from the surgery.

Where is the study run from?

EDa Hospital, Taiwan

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

The study started in June 2009 and ended in May 2011.

Who is funding the study?

EDa Hospital, 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  
dr.ckhuang@hotmail.com

# Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

EMRP-099-084

# Study information

## Scientific Title

Metabolic surgery for body mass index (BMI) < 27 kg/m<sup>2</sup> patients with type 2 diabetes mellitus: early results

## Acronym

BMI

## Study objectives

To see the effect of Surgery Laparoscopic Roux-en-Y Gastric bypass (LRYGB) on type 2 diabetes mellitus (T2DM) status on patients with BMI < 27kg/m<sup>2</sup>

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The ethics committee and Institutional Review Board of the E-Da Hospital, 11 December 2008, ref: EMRP- 097-106

## Study design

Pilot study

**Primary study design**

Interventional

**Secondary study design**

Non randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please contact Professor Chih-Kun Huang at [dr.ckhuang@hotmail.com](mailto:dr.ckhuang@hotmail.com) to request a patient information sheet

**Health condition(s) or problem(s) studied**

Type 2 diabetes Mellitus

**Interventions**

Surgery, Laparoscopic Roux-en-Y Gastric Bypass (LRYGB)

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

1. Remission of T2DM, defined by HbA1c < 6.5% without oral hypoglycemic drugs or insulin
2. Glycemic control, defined as HbA1C of < 7 % despite no use of anti-diabetic medications
3. Improvement of T2DM, defined as a reduction of at least 25% in the fasting plasma glucose level and/ or at least 1% in the pre-operative HbA1c level with hypoglycemic drug treatment
4. Failure of surgical procedure, defined as no significant improvement or worsened if a patient required an additional anti-diabetic medication

**Secondary outcome measures**

1. Resolution of co-morbidities
2. Complications related to procedure

**Overall study start date**

01/06/2009

**Completion date**

31/05/2011

**Eligibility**

**Key inclusion criteria**

1. Age 18-65 years
2. BMI < 27 kg/m<sup>2</sup>
3. Poorly controlled T2DM for at least 6 months with glycosylated haemoglobin (Hb A1C) level of >7.0%

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

21

**Key exclusion criteria**

1. Patients younger than 18 or older than 65 years
2. Those planning pregnancy in next 2 years
3. Patients with type 1 diabetes mellitus (T1DM)
4. Latent autoimmune diabetes in adults
5. Malignancy
6. Debilitating disease
7. Unresolved psychiatric illness
8. Substance abuse
9. American Society of Anesthesiologists (ASA) classification > III

**Date of first enrolment**

01/06/2009

**Date of final enrolment**

31/05/2011

**Locations****Countries of recruitment**

Taiwan

**Study participating centre**

1 E-Da Road

Kaohsiung

Taiwan  
824

## Sponsor information

### Organisation

EDa Hospital (Taiwan)

### Sponsor details

1 Yida Road  
Jiaosu Village  
Yanchao District  
Kaohsiung  
Taiwan  
82445  
ed103221@edah.org.tw

### 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

EDa 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