

Metabolic surgery for body mass index (BMI) < 27 kg/m² patients with type 2 diabetes mellitus

Submission date 06/10/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 18/10/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 27/11/2012	Condition category 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 /m². 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
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Contact information

Type(s)

Scientific

Contact name

Prof Chih Kun Huang

Contact details

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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/m² 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/m²

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 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/m²
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