

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The safety and efficacy of Laparoscopic Gastric Plication versus Laparoscopic Mini-Gastric Bypass surgery in the treatment of morbid obesity

Protocol summary

Summary

1. Objectives: In this study, we are intending to compare safety and efficacy of LGP and LMGB for the treatment of morbid obesity. 2. Setting and conduct: This study conducts at Sina hospital. 3. Design and Intervention: Forty morbid obese patients meet the National Institutes of Health (NIH) criteria, and randomly assign to receive either Laparoscopic Gastric Plication (N=20) or Laparoscopic Mini-Gastric Bypass (N=20). 4. Participants eligibility criteria: Inclusion criteria: morbid obesity (BMI>40 kg/m² or BMI>35kg/m² with co-existing morbidities); age 18 to 65; previous unsuccessful weight loss attempts Exclusion criteria: previous restrictive or malabsorptive procedure for obesity treatment; previous gastric surgery; history of anti-reflux surgery; pregnancy 5. Main outcome measured variables: early and late complications, body mass index (BMI), excess weight loss (EWL) and obesity related co-morbidities determine at one year follow-up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013012712294N1**

Registration date: **2013-02-13, 1391/11/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-13, 1391/11/25

Registrant information

Name

Reza Heydari

Name of organization / entity

School of Medicine, Tehran University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2010-03-31, 1389/01/11

Expected recruitment end date

2011-04-30, 1390/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The safety and efficacy of Laparoscopic Gastric Plication versus Laparoscopic Mini-Gastric Bypass surgery in the treatment of morbid obesity

Public title

Laparoscopic Gastric Plication versus Laparoscopic Mini-Gastric Bypass surgery in the treatment of morbid obesity

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: morbid obesity (BMI>40 kg/m² or BMI>35kg/m² with co-existing morbidities); age 18 to

65; previous unsuccessful weight loss attempts Exclusion criteria: previous restrictive or malabsorptive procedure for obesity treatment; previous gastric surgery; history of anti-reflux surgery; pregnancy

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences.

Street address

Tehran University of Medical Sciences, Corner of Ghods St., Keshavarz Blvd., Tehran, Iran.

City

Tehran

Postal code

1417613151

Approval date

2011-10-20, 1390/07/28

Ethics committee reference number

901301315

Health conditions studied

1

Description of health condition studied

Morbid obesity

ICD-10 code

E66.8

ICD-10 code description

Morbid obesity

Primary outcomes

1

Description

Operative time

Timepoint

during surgery

Method of measurement

with a clock

2

Description

length of hospitalization

Timepoint

after discharging

Method of measurement

days of hospitalization

3

Description

percent of excess weight loss

Timepoint

12 months follow-up

Method of measurement

weight

4

Description

hypertension

Timepoint

12 months follow-up

Method of measurement

clinical examination and non invasive blood pressure measurement

5

Description

Diabetes

Timepoint

12-month follow-up

Method of measurement

FBS , HgA1c

6

Description

hyperlipidemia

Timepoint

12 months follow-up

Method of measurement

cholesterol level, triglyceride

7

Description

Gastroesophageal reflux disease

Timepoint

12 months follow-up

Method of measurement

Asking the patient

8**Description**

menstrual cycle

Timepoint

12 months follow-up

Method of measurement

asking the patient

9**Description**

Degenerative joint disease

Timepoint

12 months follow-up

Method of measurement

history taking and physical exams

10**Description**

Sleep apnea

Timepoint

12 months follow-up

Method of measurement

Asking the patient

11**Description**

Depression

Timepoint

12 months follow-up

Method of measurement

Beck Depression Inventory score

12**Description**

back pain

Timepoint

12 months follow-up

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups**1****Description**

Laparoscopic Gastric Plication

Category

Treatment - Surgery

2**Description**

Laparoscopic Mini-Gastric Bypass

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina hospital.

Full name of responsible person

Mohammad Talebpour

Street addressLaparoscopic Ward, Sina Hospital, Hasanabad Sq.,
Imam Khomeini St.**City**

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research, Tehran University of
Medical Sciences**Full name of responsible person**

Dr.Akbar Fotouhi

Street addressTehran University of Medical Sciences, Corner of
Ghods St., Keshavarz Blvd., Tehran, Iran.**City**

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Tehran University of Medical
Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Laparoscopic ward, Sina Hospital, Hasanabad Sq.,

Imam Khomeini St.

Full name of responsible person

Mohammad Talebpour

Position

Head of Laparoscopic Ward/Associate Professor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty