

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The safety and efficacy of Laparoscopic Gastric Plication versus Laparoscopic sleeve gastrectomy in the treatment of morbid obesity

#### Protocol summary

##### Summary

Objectives: In this study, we are intending to compare safety and efficacy of LGP and LSG for the treatment of morbid obesity. 2. Setting and conduct: This study conducts at Sina hospital. 3. Design and Intervention: 70 morbid obese patients meet the National Institutes of Health (NIH) criteria, and randomly assign to receive either Laparoscopic Gastric Plication (N=35) or Laparoscopic sleeve gastrectomy (N=35). 4. Participants eligibility criteria: Inclusion criteria: morbid obesity ( BMI>40 kg/m<sup>2</sup> or BMI>35kg/m<sup>2</sup> 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 two year follow-up.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013123012294N5**  
Registration date: **2015-06-01, 1394/03/11**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-06-01, 1394/03/11

##### Registrant information

##### Name

Reza Heydari

##### Name of organization / entity

School of Medicine, Tehran University of Medical

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-04-08, 1391/01/20

##### Expected recruitment end date

2013-03-10, 1391/12/20

##### 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 sleeve gastrectomy in the treatment of morbid obesity

##### Public title

The safety and efficacy of Laparoscopic Gastric Plication versus Laparoscopic sleeve gastrectomy in the treatment of morbid obesity

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

morbid obesity ( BMI>40 kg/m<sup>2</sup> or BMI>35kg/m<sup>2</sup> 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

No age limit

#### Gender

Both

#### Phase

2-3

#### Groups that have been masked

No information

#### Sample size

Target sample size: 70

#### 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

percent of excess weight loss

##### Timepoint

24 months after surgery

##### Method of measurement

Weighing

#### 2

##### Description

Operative time

##### Timepoint

During surgery

##### Method of measurement

With a clock

#### 3

##### Description

length of hospitalization

##### Timepoint

after discharging

##### Method of measurement

days of hospitalization

#### 4

##### Description

hypertension

##### Timepoint

24 months follow-up

##### Method of measurement

clinical examination and non invasive blood pressure measurement

#### 5

##### Description

Diabetes

##### Timepoint

24-months follow-up

##### Method of measurement

FBS , HgA1c

#### 6

##### Description

hyperlipidemia

##### Timepoint

24 months follow-up

##### Method of measurement

cholesterol level, triglyceride

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Laparoscopic Gastric Plication

**Category**

Treatment - Surgery

**2**

**Description**

Laparoscopic Sleeve Gastrectomy

**Category**

Treatment - Surgery

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sina hospital

**Full name of responsible person**

Mohammad Talebpour

**Street address**

Laparoscopy ward, Sina hospital, Hasanabad Sq.,  
Emam Khomeini St., Tehran

**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

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

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice 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**

School of Medicine, Tehran University of Medical  
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**Full name of responsible person**

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**Position**

MD-MPH student

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Professor of surgery

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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*