

# 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**

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice chancellor for research, Tehran University of  
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**Full name of responsible person**

Dr.Akbar Fotouhi

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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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**Position**

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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*