

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of comparing of two methods of measuring the bypassed bowel based on "total small bowel length" and "Body Mass Index" on benefits and surgical complications of Laparoscopic Mini Gastric Bypass in morbid obese patients

Protocol summary

Summary

The purpose of this study is to compare the efficacy and surgical complications of laparoscopic Mini Gastric Bypass (MGB) in morbidly obese patients between two different methods in terms of measuring the bypassed bowel length and body mass index. This study is a double blinded randomized clinical trial (Phase II) which is going to run in Obesity Clinic in Rasoul-e-Akram Hospital between 2017 and 2019. Inclusion criteria are morbid obese patients (BMI higher than 40 or higher than 35 along with comorbidities) and patient aged 18-60 years. Patients with history of previous abdominal or bariatric surgery and patients with a small bowel length shorter than 300 centimeters are excluded. One hundred patients will be enrolled the study and randomized into two groups and follows at 1, 3, 6 and 12 months after surgery. Intervention group is measuring the bypassed bowel based on about one third of total small bowel length and control group is measuring the bypassed bowel based on BMI which is the standard procedure. The examined outcomes are weight loss, complications, comorbidities and malnutrition.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612118588N21**

Registration date: **2017-02-12, 1395/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-12, 1395/11/24

Registrant information

Name

Mohadeseh Pishgahroudsari

Name of organization / entity

Minimally Invasive Surgery Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 5447

Email address

research@lapsurg.ir

Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparing of two methods of measuring the bypassed bowel based on "total small bowel length" and "Body Mass Index" on benefits and surgical complications of Laparoscopic Mini Gastric Bypass in morbid obese patients

Public title

Comparing of benefits and surgical complications of Laparoscopic Mini Gastric Bypass in morbid obese patients by two methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with body mass index more than 40 or more than 35 with one obesity commodities.

Exclusion Criteria: Patients with history of previous abdominal or bariatric surgery and the patients with common channel less than 3 meters.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical sciences

Street address

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

City

Tehran

Postal code

Approval date

2016-12-28, 1395/10/08

Ethics committee reference number

IR.IUMS.REC 1395.95-03-140-28882

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

weight loss

Timepoint

Before the intervention, one month after the intervention, three months after the intervention, six months after intervention, and twelve months after intervention

Method of measurement

scale

2

Description

comorbidities of obesity

Timepoint

Before the intervention , one month after the intervention, three months after the intervention, six months, and 12 months after interventio

Method of measurement

History, Physical Exam, Lab test

3

Description

malnutrition

Timepoint

one month after the intervention, three months after the intervention, six months, and twelve months after intervention

Method of measurement

Lab Test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group after measuring the total small bowel length, almost one third of this length will be bypassed.

Category

Treatment - Surgery

2

Description

control group: In this group length of bypassed bowel is measured based on patient's body mass index.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Rasool-e-Akram Hospital

Full name of responsible person

Dr.Seyed Sattar Darabi

Street address

Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

City

Tehran

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 6655 5447

Fax**Email**

ssdarabi91@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice President of Research, Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ali Javadmousavi

Street address

Iran University of Medical sciences, south side of Hemmat highway, Tehran, Iran.

City

Tehran

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

Yes

Title of funding source

Vice President of Research, Iran 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**

Minimally Invasive Surgery Research Center, Iran University of Medical Sciences

Full name of responsible person

Dr.Seyed Sattar Drabi

Position

Fellowship of Minimally Invasive Surgery

Other areas of specialty/work**Street address**

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Minimally Invasive Surgery Research Center, Iran University of Medical sciences, Tehran, Iran

Full name of responsible person

Dr.Mohammadreza Abdolhoseini

Position

Fellowship of Minimally Invasive Surgery

Other areas of specialty/work**Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran.

City

Tehran

Postal code**Phone**

+98 21 6655 5447

Fax**Email**

mra_75@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Minimally Invasive Surgery Research Center

Full name of responsible person

Dr.Seyed Sattar Darabi

Position

Fellowship of Minimally Invasive Surgeries

Other areas of specialty/work**Street address**

Minimally Invasive Surgery Research Center, Rasool-e-Akram Hospital, Niyayesh Ave, Sattarkhan St., Tehran, Iran

City

Tehran

Postal code**Phone**

+98 21 6655 5447

Fax**Email**

ssdarabi91@yahoo.com

Web page address

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