

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of early results and complications in multiport sleeve Gastrectomy and Single port Sleeve Gastrectomy

Protocol summary

Summary

Objectives: This study aims at comparing multiport sleeve gastrectomy (MPSG) and single-port sleeve gastrectomy (SPSG) in terms of their early results and complications. Design: Patients who referred to obesity clinic in Shiraz University of Medical Sciences and be candidate for Laparoscopic Sleeve Gastrectomy, assigned in two groups to SPSG (group A) and MPSG (group B). Setting and conduct: Complications like bleeding, hernia, and internal organ injury and demographic data such as BMI, age, gender, operation time and hospital stay could be measured. Inclusion criteria: Patients with BMI ≥ 40 or $35 \leq \text{BMI} \leq 40$ with comorbidity Exclusion criteria: Patients with hypertension, sleep apnea, diabetes, history of upper abdominal operation. Intervention: In first interventional group: Single port sleeve gastrectomy surgery will be performed In second interventional group: Multi-port sleeve gastrectomy surgery will be performed Main outcome measures (variables):bleeding, hernia and internal organ injury

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512229936N12**

Registration date: **2016-03-07, 1394/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-03-07, 1394/12/17

Registrant information

Name

Leila Ghahramani

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

vice-chancellor of research-Shiraz University of Medical Sciences

Expected recruitment start date

2014-08-03, 1393/05/12

Expected recruitment end date

2015-08-03, 1394/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of early results and complications in multiport sleeve Gastrectomy and Single port Sleeve Gastrectomy

Public title

Comparison of early results and complications in multiport sleeve Gastrectomy and Single port Sleeve Gastrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion: Patients with BMI ≥ 40 or $35 \leq \text{BMI} \leq 40$

Exclusion: Patients with hypertension, sleep apnea or diabetes and history of upper abdominal operation

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Simple randomization is mentioned, same number of patients that referred to clinic in one period of time assigned in each group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

City

Shiraz

Postal code

14336 - 71348

Approval date

2014-06-03, 1393/03/13

Ethics committee reference number

7510

Health conditions studied

1

Description of health condition studied

Morbid obesity

ICD-10 code

E66.8

ICD-10 code description

Other obesity

Primary outcomes

1

Description

Weight loss

Timepoint

Before Surgery

Method of measurement

Examinations and weight of the patient

Secondary outcomes

1

Description

Bleeding

Timepoint

The day of surgery, 1 month, 3 months, 6 months after surgery

Method of measurement

Visits by Physician and nurses

2

Description

Adhesion

Timepoint

The day of surgery, 1 month, 3 months, 6 months after surgery

Method of measurement

Visits by Physician

3

Description

Leakage

Timepoint

The day of surgery, 1 month, 3 months, 6 months after surgery

Method of measurement

Visits by surgeon

4

Description

Infection

Timepoint

The day of surgery, 1 month, 3 months, 6 months after surgery

Method of measurement

Visits by surgeon

5

Description

Weight after surgery

Timepoint

The day of surgery, 1 month, 3 months, 6 months after surgery

Method of measurement

Visits by surgeon

Intervention groups

1

Description

In first group: Single port sleeve gastrectomy In Sleeve gastrectomy, a part of stomach removed and it causes decrease of food tolerance and eating. Weight loss occurred and the method differs by ports in abdomen during the surgery.

Category

Treatment - Surgery

2

Description

In second interventional group: Multi-port sleeve gastrectomy surgery will be performed In Sleeve gastrectomy, a part of stomach removed and it causes decrease of food tolerance and eating. Weight loss occurred and the method differs by ports in abdomen during the surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sahid Faghihi Hospital

Full name of responsible person

Dr Seyed Vahid Hosseini

Street address

Sahid Faghihi Hospital, Zand street, Shiraz, Iran

City

Shiraz

2

Recruitment center

Name of recruitment center

mother and child hospital

Full name of responsible person

Seyed Vahid Hosseini, Dr

Street address

mother and child hospital, Quran Blvd, Shiraz, Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor Research of Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi, Dr

Street address

Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran

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Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor Research of Shiraz 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

Colorectal Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

Full name of responsible person

Hajar Khazraei, Dr

Position

Executive manager of colorectal research center/Associated Professor

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Person responsible for scientific inquiries

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Professor

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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