

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of fascia repair and without fascia repair in incident of Trocar Site Hernia after laparoscopic gastrectomy

Protocol summary

Study aim

The aim was to compare incidence of trocar site hernia between two groups, a group with repair of fascial and without fascia repair.

Design

Patients are randomly divided into two treatment groups closure of fascia and without closure of fascia by matching BMI and sex variables.

Settings and conduct

In this clinical trial study patients undergoing Laparoscopic sleeve gastrectomy in 2019 and 2020 will be enrolled in this study.

Participants/Inclusion and exclusion criteria

In this clinical trial study patients with Laparoscopic sleeve gastrectomy will be included in the study. Exclusion criteria included patient whom wasn't appropriate for laparoscopic surgery, patient with past history of any kind of hernia, indeterminate technique in closing trocar incision, patient who undergo any other laparotomy or laparoscopic surgeries for other reasons after or before the Laparoscopic sleeve gastrectomy, patient whom laparoscopic surgery was converted to open surgery and patient who didn't sign the consent form.

Intervention groups

Treated with closure of fascia and without closure of fascia

Main outcome variables

incidence of Trocar site hernia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160803029181N11**

Registration date: **2020-06-19, 1399/03/30**

Registration timing: **retrospective**

Last update: **2020-06-19, 1399/03/30**

Update count: **0**

Registration date

2020-06-19, 1399/03/30

Registrant information

Name

Nasser Malekpour Alamdari

Name of organization / entity

Shahid Behesht University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2207 4089

Email address

nassermalekpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of fascia repair and without fascia repair in incident of Trocar Site Hernia after laparoscopic gastrectomy

Public title

The effect of fascia closure in incident of Trocar Site Hernia in laparoscopic sleeve gastrectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

- patients undergoing Laparoscopic sleeve gastrectomy - morbid obesity (BMI more than 40 kg/m² in healthy people and more than 35 kg/m² with comorbidity)

Exclusion criteria:

- patient whom wasn't appropriate for laparoscopic surgery - patient with past history of any kind of hernia - indeterminate technique in closing trocar incision - patient who undergo any other laparotomy or laparoscopic surgeries for other reasons after or before the Laparoscopic sleeve gastrectomy - patient whom laparoscopic surgery was converted to open surgery - patient who didn't sign the consent form.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **460**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two groups with closure of fascia and without by matching body mass index and sex variables. we used a randomization number table for randomization of Patients in two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and analyzers are blind to the study. The form of skin suture was the same in both groups, and the Patients and analyzers did not know what group the patients are in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics commity of Shahid Beheshti University of Medical Sciences

Street address

Daneshju Avenue Velenjak

City

Tehran

Province

Tehran

Postal code

19857174433

Approval date

2019-12-15, 1398/09/24

Ethics committee reference number

IR.SBMU.REC.1398.135

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

trocar site hernia

Timepoint

3,6,9,12 month after surgery

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group :Treated with fascia repair at site of trocar(10mm diameter, Ethicon, US, LLC) entrance by 1-0 vicryl suture (Supa, Tehran, Iran) with simple suture

Category

Treatment - Surgery

2

Description

Control group:without fascia repair at site of trocar(10mm diameter) entrance

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Modarres Hospital

Full name of responsible person

Nasser Malekpour

Street address

Modarres Hospital;Kaj Sq;Saadat Abad;

City

Tehran

Province

Tehran

Postal code

1998734383

Phone

+98 21 2206 9355

Fax

+98 21 2206 9355

Email

nassermalekpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Ali Ziai

Street address

Danshju Ave Velenjak

City

Tehran

Province

Tehran

Postal code

1998734383

Phone

+98 21 2207 4087

Fax

+98 21 2207 4087

Email

aliziai@sbm.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nasser Malekpour Alamdari

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Shahid Beheshti University of Medical Sciences, Arabi street, Velenjak.

City

Tehran

Province

Tehran

Postal code

1998734383

Phone

+98 21 2207 4089

Fax

+98 21 2207 4101

Email

nassermalekpour@sbm.ac.ir

Person responsible for scientific inquiries

Contact

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Contact

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Shahid Beheshti University of Medical Sciences
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Nasser Malekpour Alamdari
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Shahid Beheshti University of Medical Sciences, Arabi
street, Velenjak
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2207 4089
Fax

+98 21 2207 4101
Email
nassermalekpour@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available