

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of recurrence rate and pain severity in patients with incisional hernia in open and laparoscopic methods

Protocol summary

Study aim

Comparison of recurrence rate and pain severity in patients with incisional hernia in open and laparoscopic methods

Design

Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 70 patients undergoing incisional hernia surgery

Settings and conduct

This study will be conducted with the aim of comparison of recurrence rate and pain severity in patients with incisional hernia in open and laparoscopic methods on 70 patients attending Shahid Modarres hospital in Tehran city. After inclusion in the study, the patients will be assigned into two groups; open group and laparoscopic group. Pain severity will be assessed using Visual Analogue Scale (VAS) 3 days, one week and 4 weeks after the surgery and recurrence rate will be evaluated by asking the patients and the results will be compared together in the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criterion: having incisional hernia with a 3-15 cm diameter Exclusion criteria: having contraindication for anesthesia; having immunosuppression; having intestinal obstruction

Intervention groups

Intervention group 1: surgery using open method
Intervention group 2: surgery using laparoscopic method

Main outcome variables

Recurrence rate Pain severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161217031440N3**

Registration date: **2021-10-14, 1400/07/22**

Registration timing: **prospective**

Last update: **2021-10-14, 1400/07/22**

Update count: **0**

Registration date

2021-10-14, 1400/07/22

Registrant information

Name

Barmak Gholizadeh

Name of organization / entity

Shahid beheshti university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 2298 6403

Email address

b_gholizadeh@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-17, 1400/07/25

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of recurrence rate and pain severity in patients with incisional hernia in open and laparoscopic methods

Public title

Comparison of recurrence rate and pain severity in patients with incisional hernia in open and laparoscopic methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having incisional hernia with a 3-15 cm diameter

Exclusion criteria:
Having contraindication for anesthesia Having immunosuppression Having intestinal obstruction

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are randomly assigned into two groups (open and laparoscopic) using a random number table. A random number table containing unrepeated numbers between 1 and 70 is selected and the reading is started from the left. If the number is odd the patient is assigned into open group and if the number is even the patient is assigned into laparoscopic group.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person evaluating the patients is not aware of patients assignment and so is blinded.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Third Floor, School of Medicine, Aarabi st., Yaman st., Shahid Chamran hwy.

City

Tehran

Province

Tehran

Postal code

1939547191

Approval date

2020-12-15, 1399/09/25

Ethics committee reference number

IR.SBMU.MSP.REC.1399.468

Health conditions studied

1

Description of health condition studied

Incisional hernia

ICD-10 code

K43.0

ICD-10 code description

Incisional hernia with obstruction, without gangrene

Primary outcomes

1

Description

Recurrence rate

Timepoint

One year after the surgery

Method of measurement

By asking the patient about the recurrence

2

Description

Pain severity

Timepoint

3 days, one week and 4 weeks after the surgery

Method of measurement

By using Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: surgery using open method

Category

Treatment - Surgery

2

Description

Intervention group 2: surgery using laparoscopic method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person
Barmak Gholizadeh
Street address
Shahid Modarres hospital, Saadat abad st.
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zargi
Street address
3rd Floor, School of Medicine, Arabi st., Yaman st.,
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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

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

Barmak Gholizadeh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available