

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Comparative study of the effect of fixation mesh and non-fixation of mesh (Use of external fixation (hernia band) after surgery) in causing postoperative complications in patients with inguinal hernia undergoing laparoscopic hernioplasty

Protocol summary

Study aim

Determining and comparing the effect of internal mesh fixation and non-mesh fixation (using external fixation) in causing complications after hernioplasty surgery

Design

Randomized, Single-blinding clinical trial, with the parallel groups, Phase 3 on 64 patients

Settings and conduct

In this randomized, single-blind randomized clinical trial study, 64 patients with inguinal hernia referred to Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into 2 groups. Laparoscopic surgery is used in both groups. In one group the mesh is fixed for patients and in the other group the mesh is not fixed internally and the patient uses a hernia band after surgery. Patients' complications will then be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include having an inguinal hernia and consent to participate in the study. Exclusion criteria include having one of the incarcerated, strangulated, very large (scrotal) or femoral inguinal hernias.

Intervention groups

Control group: Patients in this group are treated for inguinal hernia repair by laparoscopic method and for these patients the mesh is fixed internally (using suture or tack). Intervention group: Patients in this group are treated for inguinal hernia repair by laparoscopic method and for these patients the mesh is not fixed and after the operation, an external hernia is used.

Main outcome variables

Seroma incidence; Hematoma incidence; Recurrence of hernia; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N25**

Registration date: **2021-03-17, 1399/12/27**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-17, 1399/12/27**

Update count: **0**

Registration date

2021-03-17, 1399/12/27

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-07, 1399/11/19

Expected recruitment end date

2021-04-18, 1400/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of fixation mesh and non-fixation of mesh (Use of external fixation (hernia band) after surgery) in causing postoperative complications in patients with inguinal hernia undergoing laparoscopic hernioplasty

Public title

Comparison of the effect of fix and non-fix mesh (Use of external fixation (hernia band) after surgery) in causing complications after hernioplasty surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having an inguinal hernia Satisfaction with participation in this study

Exclusion criteria:

Having an incarcerated hernia Having a strangulated hernia Having a very large inguinal hernia (scrotal) Having a femoral inguinal hernia

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 64 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into two parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the two groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the present study, the surgeon is aware of the type of surgery in each of the two groups, but the patient and the evaluator (data collector) are not aware of the type of surgery in each group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.MUI.MED.REC.1399.825

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40.3

ICD-10 code description

Unilateral inguinal hernia, with obstruction, without gangrene

Primary outcomes

1

Description

Seroma

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Observation

2

Description

Hematoma

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Observation

3

Description

Pain

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description

Recurrence of hernia

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Observation

Intervention groups

1

Description

Control group: Patients in this group are treated for inguinal hernia repair by laparoscopic method and for these patients the mesh(Bard 3D Max) is fixed internally (using Vicryl suture 2-0).

Category

Treatment - Surgery

2

Description

Intervention group: Patients in this group are treated for inguinal hernia repair by laparoscopic method and for these patients the mesh is not fixed and after the operation, an external hernia(Paksaman) is used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Masoud Sayadi Shahraki

Street address

Department of Surgery, Al-Zahra Hospital

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

sayadi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Masoud Sayadi Shahraki

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Al-Zahra Hospital, Department of Surgery

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone
+98 31 3620 2020
Email
sayadi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Masoud Sayadi Shahraki
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Al-Zahra Hospital, Department of Surgery
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
sayadi@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person

Zakaria Sharbu
Position
Non-faculty specialist physician
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Al-Zahra Hospital, Department of Surgery
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
dr.zsharbu82@gmail.com

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

There is no further 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