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
Isfehan

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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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
Isfehan
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