Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment outcomes of surgical repair in inguinal hernia with classic versus preperitoneal methods on patient satisfaction and reduction of postoperative complications

Protocol summary

Summary

Usually inguinal herniorrhaphy with mesh is done by two classic and pre-peritoneal methods. Our aim is to compare these two surgery methods in the candidate patients for inguinal herniorrhaphy. Our study community includes candidate patients for inguinal herniorrhaphy with mesh. Inclusion criteria: having hernia, candidate for classic herniorrhaphy, candidate for pre-peritoneal herniorrhaphy, satisfaction to enter to study. Exclusion criteria: diabetes, bleeding disorders, aspirin and corticosteroid consumption. In both groups, the surgeon will incise the skin and subcutaneous tissue of lower part of abdomen and then Scarpa fascia and the roof of inguinal canal. Then, in the first group the floor of canal will be repaired and the mesh will be located on the floor of canal and in the other group, the mesh will be installed under the canal and then the floor will be repaired. Both groups will be compared after surgery according to recurrence, pain, seroma and hematoma in 3 to 12 months periods.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016030826974N1**
Registration date: **2016-06-07, 1395/03/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-07, 1395/03/18

Registrant information

Name

Shahab Forutani

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 936 656 6615

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2015-06-01, 1394/03/11

Expected recruitment end date

2016-06-01, 1395/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment outcomes of surgical repair in inguinal hernia with classic versus preperitoneal methods on patient satisfaction and reduction of postoperative complications

Public title

Comparison treatment outcomes use of two classic and preperitoneal surgery methods in inguinal hernia repair

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: having inguinal hernia, candidate for

classic herniorrhaphy, candidate for preperitoneal herniorrhaphy, satisfaction to enter to study. Exclusion criteria: diabetes, bleeding disorders, aspirin and corticosteroid consumption.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Block design

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Kamalvand street, Khorramabad, Lorestan

City
Khorramabad

Postal code

Approval date
2016-03-08, 1394/12/18

Ethics committee reference number
lums.rec.1394.62

Health conditions studied

1

Description of health condition studied
inguinal herniorrhphy

ICD-10 code
k40

ICD-10 code description
Hernia with both gangrene and obstruction is classified to hernia with gangrene

Primary outcomes

1

Description
pain

Timepoint
Before intervention and two months after intervention

Method of measurement
questionnaire

2

Description
Duration of operation

Timepoint
after intervention

Method of measurement
Clock-Patient case

Secondary outcomes

1

Description
recurrence

Timepoint
3, 4, 5, 6 and 12 months after intervention

Method of measurement
questionnaire

2

Description
hematoma

Timepoint
3, 4, 5 and 6 months after intervention

Method of measurement
questionnaire

3

Description
seroma

Timepoint
3, 4, 5 and 6 months after intervention

Method of measurement
questionnaire

4

Description
patient satisfaction rate

Timepoint
6 months after intervention

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention group 1: candidate patients for inguinal henniorrhaphy with pre-peritoneal method. In this method, mesh is inserted on the peritoneum layer
Category
Treatment - Surgery

2

Description
Intervention group 2: candidate patients for inguinal henniorrhaphy with classic method. This method is a free tension procedure to repair which employs artificial materials (mesh) to construct the floor of inguinal canal. Mesh is inserted on the anterior surface of Transversalis fascia
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Ashayer hospital
Full name of responsible person
Dr.Hormoz Mahmoudvand
Street address
City
Khorramabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Lorestan University of Medical Sciences
Full name of responsible person
Dr.Taheri kalani
Street address
Kamalvand street, Khorramabad, Lorestan
City
Khorramabad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research of Lorestan 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
Lorestan University of Medical Sciences
Full name of responsible person
Dr.Hormoz Mahmoudvand
Position
Phd Of general surgery
Other areas of specialty/work
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Person responsible for updating data

Contact
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Shahab Forutani
Position
student

Other areas of specialty/work

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City

Khorramabad

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Phone

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Fax

Email

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Web page address

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