

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 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

Email address

shahabforutani@yahoo.com

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 herniorrhaphy

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 herniorrhaphy 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 herniorrhaphy 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

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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 scientific inquiries

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Position

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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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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