Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A clinical trial on the outcomes of Read-Rives and Lichtenstein surgical procedures for inguinal hernia in patients with unilateral inguinal hernia

Protocol summary

Summary

This study aims to compare the outcomes of two surgical procedures, namely, Lichtenstein and Read-Rives in patients with unilateral inguinal hernia. All patients with inguinal hernia referring to the surgery clinic of Imam Reza Hospital affiliated with Birjand University of Medical Sciences in 2017 will be incorporated into the study. Major inclusion criteria are age 19 years or older, indications for inguinal hernia surgery and consent to participate in the study. The study is in Phase II and single-blinded, where the participants are unaware of which treatment group they belong. A total of 70 patients will be selected by convenience sampling method and will be assigned into either of the surgical groups via simple randomization method (35 patients per group). The first intervention group will be operated using the Lichtenstein procedure, whereas the second intervention group will undergo Read-Rives procedure. All the participants will be visited on the first postoperative day and would be discharged if there is an absence of severe pain, hematoma and seroma. The patients will be visited a week and two weeks after the operation, and the required information concerning the outcomes will be recorded using a checklist. The outcomes comprise of operation length, length of hospital stay after surgery, recovery time, pain severity, wound infection, mesh infection, hematoma, seroma, and skin sensitivity in the operation site.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061317756N19**
Registration date: **2017-06-18, 1396/03/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-18, 1396/03/28

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellery for Research, Birjand University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial on the outcomes of Read-Rives and Lichtenstein surgical procedures for inguinal hernia in patients with unilateral inguinal hernia

Public title

Comparison of the outcomes of Lichtenstein and Read-Rives surgical procedures in patients with unilateral inguinal hernia

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Minimum age of 19 years and above; indications for inguinal hernia surgery; provision of informed consent. Exclusion criteria: unwillingness to continue the study; incarcerated hernia; strangulated hernia; sliding hernia; bilateral hernia.
Age
From **19 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Vice-chancellery of Research and Technology, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand
Postal code
Approval date
2016-09-17, 1395/06/27
Ethics committee reference number
IR.BUMS.REC.1395.81

Health conditions studied

1

Description of health condition studied
unilateral inguinal hernia
ICD-10 code
K40.9
ICD-10 code description
Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
Mean operation length
Timepoint
From the beginning to the end of the surgery
Method of measurement
minute

2

Description
Pain severity
Timepoint
On a daily basis during hospitalization
Method of measurement
Visual Analogue Scale

3

Description
Length of postoperative hospitalization
Timepoint
From the operation day to discharge
Method of measurement
day

4

Description
Wound infection frequency
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Clinical examination

5

Description
Mesh infection
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Clinical examination

6

Description
Hematoma
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Clinical examination

7

Description
Seroma
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Clinical examination

8

Description
Infection of operation site
Timepoint
During hospitalization, first and second weeks after operation
Method of measurement
Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group 1 (Lichtenstein Tension-Free Mesh Repair): After primary open incision and dissection of spermatic cord, the hernia sac will be identified and isolated. A 7.5 × 15 cm piece of polypropylene mesh will be placed on posterior wall of inguinal canal. The first medial-most stitch fixes the mesh 2 cm medial to the pubic tubercle, where the anterior rectus sheath inserts into the pubic bone. The same suture is then used as a continuous suture to fix the lower edge of the mesh to the free lower border of inguinal ligament up to a point just lateral to the internal ring. With the mesh kept lax, its upper edge is then fixed to the rectus sheath and the internal oblique aponeurosis with two or three interrupted nonabsorbable sutures. The two tails are then tucked together and fixed to the inguinal ligament just lateral to the internal ring, thus creating a new internal ring made of mesh.
Category
Treatment - Surgery

2

Description
Intervention Group 2 (Read-Rives procedure): Read-Rives procedure is performed through the longitudinal opening in the transversalis fascia in the inguinal floor. At first, the prepritoneal space is dissected and the spermatic cord is parietalized. Afterwards, a 10×15 cm of mesh is implanted in front of the peritoneum, and the mesh is held in place with 2/0 nylon sutures to pubic tubercle, cooper ligament, and psoas muscle. Finally, the fascia is closed over the mesh.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
General Surgery Clinic of Imam Reza Hospital
Full name of responsible person
Street address
Imam Reza Hospital, Taleghani St.,
City
Birjand

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research, Birjand University of Medical Sciences
Full name of responsible person
Dr.Tooba Kazemi
Street address
Vice-chancellery of Reasearch and Technology, Birjand University of Medical Sciences, Ghaffari St.,
City
Birjand
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, Birjand 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
Birjand University of Medical Sciences
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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