

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between results of "Lichtenstein", "Read-Rives" and "MCvay" repair for treatment of unilateral inguinal hernia in patients referring to Arak university of medical science's hospitals

Protocol summary

Study aim

Comparison between results of "Lichtenstein", "Read-Rives" and "MCvay" repair for treatment of unilateral inguinal hernia

Design

Three arm parallel groups, randomized clinical trial

Settings and conduct

At first, patients with unilateral inguinal hernia referred to educational hospitals affiliated to Arak University of Medical Sciences and randomly selected by the table of random numbers, will be allocated to three groups (Lichtenstein', "Read-Rives" and "MCvay"). All patients will receive 1 gr IV cefazolin before surgery. All patients will undergo general or spinal anesthesia, and the skin will be prepared routinely. Then, the steps of the surgery, according to the Lichtenstein, Read Rives, and McWay protocols, will be performed in three groups separately. All patients will undergo surgery by a single surgeon (Resident of Surgery). In all patients, cefazolin 1 gr IV will be continued for 24 to 48 hours every 8 hours, and afterwards patients will receive cap. cefalexin 500 milligrams every 6 hours until one week after surgery. All patients in all three groups will undergo postoperative visit on the first day and the first week after surgery.

Participants/Inclusion and exclusion criteria

inclusion criteria: Men between age 18-75 years, affected by unilateral inguinal hernia and without any complication, Having consent for participation in the study Exclusion criteria: Affected by incarcerated, recurrence and bilateral hernia.

Intervention groups

All patients will allocate to three intervention groups (Lichtenstein', "Read-Rives" and "MCvay").

Main outcome variables

Early postoperative complications: Acute pain, urinary retention, hematoma scrotal, hematoma ulcer, serum and wound infection.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190511043548N1**

Registration date: **2019-06-02, 1398/03/12**

Registration timing: **prospective**

Last update: **2019-06-02, 1398/03/12**

Update count: **0**

Registration date

2019-06-02, 1398/03/12

Registrant information

Name

Mohammad Jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5554 9120

Email address

m4_rezaei@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between results of "Lichtenstein", "Read-Rives" and "Mcvay" repair for treatment of unilateral inguinal hernia in patients referring to Arak university of medical science's hospitals

Public title

Comparison between results of three different repair methods of unilateral inguinal hernia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men between age 18-75 years Affected by unilateral inguinal hernia and without any complication Having consent for participation in the study (participants must be signed written consent form)

Exclusion criteria:

Affected by incarcerated hernia Affected by recurrence hernia Affected by bilateral hernia $MBI \geq 35$ Having concurrent abdominal surgery Steroid therapy Anti-platelet and anti-coagulant therapy Having drug abuse history Having liver cirrhosis Hypersensitivity to Mesh or immune system deficiency

Age

From **18 years** old to **75 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to 'Lichtenstein', 'Read-Rives' and 'Mcvay' groups according to table of random numbers. To use random number table, the researcher will first set the table numbers to read (for example, up, down, left, or right), then numbers will be considered for different groups (for example, taking 00-48 for intervention A (Lichtenstein method), numbers 49-96 for intervention B (Read-Rives method), and numbers 97-144 for group C (Mcvay method). Then the researcher will put his hand on one of the numbers and moves in one of the predefined directions and records the numbers and assigns them to different groups.

Blinding (investigator's opinion)

Not 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 Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Province

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Postal code

3819693345

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.ARAKMU.REC.1396.36

Health conditions studied

1

Description of health condition studied

Unilateral inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

Unilateral inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

Early postoperative complications (Acute pain, urinary retention, hematoma scrotal, hematoma ulcer, serum and wound infection).

Timepoint

All patients in all three groups will undergo postoperative visit on the first day and the first week after surgery.

Method of measurement

Observation and checklist- Pain will measure by 0-10 Numeric Pain Rating Scale.

Secondary outcomes

1

Description

Late postoperative complications (Sensory disturbances, testicular atrophy, testicular pain, inguinal discomfort, pain during exertion, and relapse 9 months after surgery).

Timepoint

9 month after surgery

Method of measurement

Check list and observation- Pain will measure by 0-10
Numeric Pain Rating Scale.

Intervention groups

1

Description

Intervention group: Lichtenstein technique (This method is one of the anterior tension free techniques in inguinal hernia repair that mesh is placed between internal and external oblique muscles and in front of transversalis fascia)

Category

Treatment - Surgery

2

Description

Intervention group: Read-Rives technique (This method is one of the tension free techniques in inguinal hernia repair that mesh is placed under transversalis fascia and on the peritoneum)

Category

Treatment - Surgery

3

Description

Intervention group: MC vay technique (This method is one of inguinal hernia repair techniques that inguinal and femoral defects is repaired with together)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational hospitals' affiliated to Arak university of medical sciences

Full name of responsible person

Miss Khodadadi- Vice Chancellor of Research & Technology

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Mohammad Jafari

Position

Surgery resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable