Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of mesh fixation and non-fixation in laparoscopic inguinal hernia repair

Protocol summary

Study aim
Comparison of fixation and non-fixation of mesh in laparoscopic repair of inguinal hernia

Design
Clinical trial, with parallel groups, two-way blind, randomized , About 100 patients who randomized by the blocking method and using online software www.sealedenvelope.com .

Settings and conduct
100 patients who are candidates for laparoscopic inguinal hernia surgery in Vali-e-Asr Hospital in Arak are divided into two groups. The study is double-blind and the intervention will be performed in the operating room while the patient is under general anesthesia and the patient and the outcome evaluator and data analyzer are not aware of the study groups. The first group will insert the mesh without fixing it in the peritoneum and the second group will insert the mesh by fixing it to the peritoneum. Then, after the surgery, the desired outcomes will be evaluated and compared in two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidate for laparoscopic inguinal hernia repair surgery. exclusion criteria: liver, kidney, heart disease, history of drug use, chronic analgesia

Intervention groups
In the non-fixed mesh group, after surgery, the patient will have a fibrin mesh at the hernia site in the peritoneal wall and the two edges of the peritoneum will be fused at the surgical site, but the mesh will not be fused to the peritoneum. But in the second group, after surgery for the patient in the final stage, after placing a fibrin mesh at the site of the hernia in the peritoneal wall, in addition to the two edges of the peritoneum will be screwed on it at the surgical site, the mesh itself will be screwed to the peritoneum.

Main outcome variables
Pain, urinary retention, length of hospital stay

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210224050491N1**
Registration date: **2021-03-08, 1399/12/18**
Registration timing: **prospective**

Last update: **2021-03-08, 1399/12/18**
Update count: **0**

Registration date
2021-03-08, 1399/12/18

Registrant information
Name
ghasem mehri
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 86 3417 3630
Email address
ghasemmehri1@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-03-21, 1400/01/01
Expected recruitment end date
2021-08-23, 1400/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of mesh fixation and non-fixation in laparoscopic inguinal hernia repair

Public title
Comparison of mesh fixation and non-fixation in laparoscopic inguinal hernia repair
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Candidate patients for laparoscopic inguinal hernia repair surgery referred to Vali Asr Hospital in Arak
Exclusion criteria:
History of kidney, liver and heart disease History of drug use Chronic use of painkillers
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 100 patients who meet the inclusion criteria will be divided into two completely equal groups (50 people) using block randomization method and online software www.sealedenvelope.com and using 10 blocks of 10. . Concealment will be done using the sealed opaque envelope method. In this way, the created sequences will be placed in pots with dark cover and will be sealed, and in order to maintain a random sequence, the numbering on the outer surface of the envelopes will be done in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order and the assigned group of the participant is revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be double-blind. In this way, patients will be meshed in the operating room during anesthesia for both groups and patients will not be aware of the type of meshing performed. Also, the outcome assessor recognizes the study groups only on the basis of the letters A and B and is not aware of the intervention performed, and only the surgeon and the resident resident are aware of the study groups and the type of their intervention.
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
Payambar-e-azam Complex, Sardasht Town
City
Arak
Province
Markazi
Postal code
3848176341
Approval date
2021-01-24, 1399/11/05
Ethics committee reference number
IR.ARAKMU.REC.1399.307

Health conditions studied

1

Description of health condition studied
inguinal hernia
ICD-10 code
K40
ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
Recurrence of the disease
Timepoint
1 month, 3 months and 6 months after intervention
Method of measurement
Physical examination

Secondary outcomes

1

Description
Pain
Timepoint
1 hour, 6 hours and 24 hours after surgery
Method of measurement
Visual Analogue Scale of pain

2

Description
Length of hospital stay
Timepoint
Time of discharge from the hospital
Method of measurement
Patient hospitalization file

3

Description
Urinary retention
Timepoint
1 hour, 6 hours and 24 hours after surgery
Method of measurement
Patient history

Intervention groups

1

Description
Intervention group: After performing surgery for the patient in the final stage, after placing a fibrin mesh in the hernia site in the peritoneal wall, in addition to the two edges of the peritoneum will be sutured on the surgical site, the mesh itself will be sutured to the peritoneum
Category
Treatment - Surgery

2

Description
Control group: In the control group, after surgery for the patient, in the final stage, a fibrin mesh will be placed at the hernia site in the peritoneal wall and two edges of the peritoneum will be bent on it at the surgical site, but the peritoneal mesh will not be sutured.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr hospital
Full name of responsible person
Ghasem Mehri
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Valiasr Sq.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Ghasem Mehri
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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