

# 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](http://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](http://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

**Street address**

Valiasr Sq.

**City**

Arak

**Province**

Markazi

**Postal code**

۳۸۱۹۶۹۳۳۴۰

**Phone**

+98 86 3417 3630

**Email**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Alireza Kamali

**Street address**

Payambar-e-azam Complex, Sardasht Town

**City**

Arak

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3848176341

**Phone**

+98 86 3417 3639

**Email**

research@arakmu.ac.ir

**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**

General Surgery

**Street address**

Valiasr hospital

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Arak

**Province**

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**Postal code**

3814957558

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**Email**

ghasemmehri1@gmail.com

## Person responsible for scientific 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**

General Surgery

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## Person responsible for updating data

**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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Arak

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**Postal code**

3814957558

**Phone**

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**Fax**

**Email**

ghasemmehri1@gmail.com

## 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