Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of outcomes and complications of mesh fixation and non-fixation in laparoscopic Transabdominal prepritoneal inguinal hernia repair in patients with primary inguinal hernia

Protocol summary

Study aim

Determination and comparison of results and complications of mesh fixation and non-fixation in inguinal hernia surgery by the laparoscopic transperitoneal peritoneal method in patients with primary inguinal hernia

Design

The study will be divided into two groups of fixation and non-fixation. The size of each group will be 56 people. Randomization with random blocks will be done by statistical software. The Phase 4 clinical trial study will be performed on 112 patients.

Settings and conduct

Patients with a primary inguinal hernia who are candidates for surgery by laparoscopic transperitoneal peritoneal will be divided into two groups. The surgical procedure will be different for patients. Patients' postoperative pain information will be collected using the Visual Analog Scale.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with primary inguinal hernia Inclusion criteria: age under 18, dementia and other psychological disorders, the impossibility of proper follow-up of the patient, contraindication to general anesthesia, contraindication to laparoscopic surgery, bilateral cases, recurrent cases, previous abdominal surgery history and intra-abdominal adhesion, Drugs abuse, use of neuropsychiatric drugs, liver and kidney diseases Exclusion criteria: dissatisfaction with continued cooperation, the need to change the surgical procedure to open surgery

Intervention groups

Patients with a diagnosis of primary inguinal hernia who are candidates for laparoscopic transperitoneal peritoneal surgery are included in the study. Surgery will be performed in two groups with mesh fixation and without mesh fixation.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210309050650N2**
Registration date: **2021-11-06, 1400/08/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-06, 1400/08/15**
Update count: **0**

Registration date

2021-11-06, 1400/08/15

Registrant information

Name

Naser Keikhali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3313 1851

Email address

nkeikhali@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of outcomes and complications of mesh fixation and non-fixation in laparoscopic Transabdominal prepritoneal inguinal hernia repair in patients with primary inguinal hernia

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with primary inguinal hernia

Exclusion criteria:

Age under 18 years Dementia and other psychological disorders Impossibility of proper follow-up of the patient Contraindications to general anesthesia Contraindications Laparoscopic surgery Bilateral inguinal Hernia The hernia has recurred History of previous abdominal surgery and intra-abdominal adhesions drug abuse Taking psychiatric drugs Liver and kidney diseases

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized block is used to randomize the patients under study and to fully observe the randomness of placement in the control group and the sample group because the inclusion process requires randomization due to the ongoing recruitment. Based on the calculated sample size, the sample size in each group is 24 people for easier application of random blocks to randomize the members of each group. Permutations are considered as 6 permutations according to 2 groups: AABB, ABAB, BBAA, BABA, BAAB, ABBA. The permutations are written on 6 cards and the selection of permutations and their order will be randomly selected from among the cards. The order of exit of the cards is written and will determine the order of recruitment of intervention groups based on it. An individual randomization unit will be used for the study. The information of the registered persons will be anonymous and without their personal information.

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 Zanjan University of Medical Sciences

Street address

Ayatollah Mousavi Hospital

City

Zanjan

Province

Zanjan

Postal code

4513956183

Approval date

2021-10-26, 1400/08/04

Ethics committee reference number

IR.ZUMS.REC.1400.343

Health conditions studied

1

Description of health condition studied

Primary inguinal hernia

ICD-10 code

K40.90

ICD-10 code description

Unilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent

Primary outcomes

1

Description

Postoperative pain in patients

Timepoint

Patients' pain will be assessed on days 2, 7 and the third and sixth months after surgery.

Method of measurement

Based on Visual Analogue Scale scale, data would be collected.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the peritoneum is first cut on the middle umbilical ligament so that this incision is 3-4 cm above the hernia defect and extends laterally to the upper anterior iliac spine. After removal and ligation of the sac hernia, the mesh used is usually 10 x 15 so that it can completely cover the myopectineal hole. After fixing the 3D mesh, the mesh will not be fixed. The arched position of the mesh will allow the mesh to fit properly. Finally, the peritoneum is completely closed to prevent the intestines from hitting the mesh.

Category

Treatment - Surgery

2

Description

Control group: In this group, the peritoneum is first cut on the middle umbilical ligament so that this incision is 3-4 cm above the hernia defect and extends laterally to the upper anterior iliac spine. After removal and ligation of the sac hernia, the mesh used is usually 10 x 15 so that it can completely cover the myopectineal hole. After placing the 3D mesh, the mesh will be fixed to the Cooper ligament with the help of a spiral tucker. Finally, the peritoneum is completely closed to prevent the intestines from hitting the mesh. The number of Tackers required to do this will vary in patients.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Naser Keikhali

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Zanjan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Shoghli

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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

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Naser Keikhali

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Email

nkeikhali@zums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Naser Keikhali

Position
Associate professor

Latest degree
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Other areas of specialty/work
General Surgery

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Person responsible for updating data

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Position
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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