

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the complications of oblique external flap procedure and mesh for the repair of the channel in inguinal hernia's patients

Protocol summary

Study aim

Comparison of the complications of oblique external flap procedure and mesh for the repair of the channel in inguinal hernia's patients

Design

This study is a double-blind randomized clinical trial with a sample size of 50 patients, 25 people in each group (intervention and control). Because it is not possible to blind the surgeon to the intervention, only the participants and the statistical analyzer will be blind to the intervention and outcomes. We randomized patients in 2 groups with Rand Excel function software.

Settings and conduct

The intervention will be performed in the operating room of Imam Reza Hospital in Tabriz. The 50 patients selected by simple random sampling using a computer-generated random number table are divided into two treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with a straight inguinal hernia with a loose canal floor. Exclusion criteria: patients with a history of inguinal hernia surgery; elderly people with weak external oblique fascia; patients with a history of mesh implantation.

Intervention groups

Intervention group 1: In this intervention, patients with loose inguinal canal floor will be repaired using the oblique external flap. Intervention group 2: In this intervention, patients with loose inguinal canal floor will be repaired using mesh.

Main outcome variables

The rate of pain postoperative surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211129053215N1**

Registration date: **2022-03-07, 1400/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-07, 1400/12/16**

Update count: **0**

Registration date

2022-03-07, 1400/12/16

Registrant information

Name

Siyamak Khasteh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3549 8101

Email address

siya.shapke@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-11, 1400/11/22

Expected recruitment end date

2023-02-11, 1401/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the complications of oblique external flap procedure and mesh for the repair of the channel in inguinal hernia's patients

Public title

Effect of oblique external flap and mesh on inguinal

hernia's patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with a straight inguinal hernia with a loose canal floor
Exclusion criteria:
 Patients with a history of inguinal hernia surgery Elderly people with weak external oblique fascia Patients with a history of mesh implantation

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Block method 4 was used to determine the allocation sequence. White envelopes are used to hide the allocation sequence. In this way, each sequence is placed inside a white envelope and the envelopes are arranged side by side and we number the letters to don't be disorganized. For each eligible participant, an envelope will be opened and assigned to the desired group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and analysts of research data will be blind to the type of intervention and outcome. Patients are only aware of approved standard surgical repair, regardless of the type of hernia repair method. Also, because patients' analytical identities will be recorded based on patient numbering and numbering of the type of intervention and consequences, the data analyst will be blinded. patients will be included in the intervention or control group, respectively, and the patient number is in fact the patient's analytical identity. The intervention group is assigned the number 1 and the control group the number 2, and also for the outcomes under study, the numbers 1 to 5 are assigned, respectively.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Azadi Blvd, Resalat Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5173865955

Approval date

2021-04-12, 1400/01/23

Ethics committee reference number

IR.TBZMED.REC.1400.062

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

Pain

Timepoint

One day after surgery, 6 months after surgery, 12 months after surgery

Method of measurement

Interview with the patient

Secondary outcomes

1

Description

Recurrence of hernia

Timepoint

6 months after surgery, 12 months after surgery

Method of measurement

Perform ultrasound

2

Description

Infection of surgery site

Timepoint

6 months after surgery, 12 months after surgery

Method of measurement

Ultrasound

3

Description

Post operative hematoma

Timepoint

During the week after surgery

Method of measurement

Perform ultrasound

4

Description

Feeling of a foreign body at the operation site

Timepoint

Post operative surgery

Method of measurement

Interview with the patient

Intervention groups

1

Description

Intervention group 1: In this intervention, patients with loose inguinal canal floor will be repaired using the oblique external flap.

Category

Treatment - Surgery

2

Description

Intervention group 2: In this intervention, patients with loose inguinal canal floor will be repaired using mesh.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Afshar Zomorodi

Street address

Daneshgah Street

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5166614756

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imamreza@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Akbar Khaleghi

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research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Elham Jahantabi

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Afshar Zomorrodi

Position

Professor

Latest degree

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information to give.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person