

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of mesh fixation and non-fixation in laparoscopic transabdominal preperitoneal repair (TAPP) of inguinal hernia

Protocol summary

Study aim

Determination and comparison of complications of fixation and non-fixation in laparoscopic transabdominal preperitoneal repair (TAPP) of inguinal hernia

Design

This study is a clinical trial with control group, Double Blinds, with parallel groups, and Randomization.

Settings and conduct

This was a study on the patients candidated for inguinal hernia repair surgery by laparoscopic method in Isfahan Alzahra Hospital. Samples were 86 patients with inguinal hernia that undergone inguinal hernia repair using mesh by laparoscopic transabdominal preperitoneal repair technique. Pain level was measured in patients based on VAS criterion one day after surgery, when releasing the hospital, one and two weeks and one and 6 months after surgery in both groups. In addition, early and late complications including seroma, urinary tract infection, wound infection, mesh infections, urinary retention, and relapse were evaluated in these patients in the first week after surgery and in two weeks, one month, and six months after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: No history of hernia repair surgery, No history of laparotomy, No strangulated or incarcerated hernia, Were satisfied to participate in the study.

Exclusion criteria: Cancellation of the surgery for any reason, Occurrence of unwanted complications during the surgery resulting in serious complications or death, Non-referral of the patient in post-operative follow-up for any reasons, Dissatisfaction to continue the collaboration in the present study.

Intervention groups

Patients with inguinal hernia requiring surgery undergo inguinal hernia repair using mesh by laparoscopic transabdominal preperitoneal repair technique. group1: Mesh was fixed using suture. group2: Mesh was not fixed.

Main outcome variables

Hernia relapse rate, Pain rate, Early and late complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190204042618N4**

Registration date: **2019-04-24, 1398/02/04**

Registration timing: **retrospective**

Last update: **2019-04-24, 1398/02/04**

Update count: **0**

Registration date

2019-04-24, 1398/02/04

Registrant information

Name

najme bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 8235

Email address

st_bagherin@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-24, 1396/09/03

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

2017-12-01, 1396/09/10

Actual recruitment end date

2018-03-01, 1396/12/10

Trial completion date

2018-06-22, 1397/04/01

Scientific title

Comparison of the effect of mesh fixation and non-fixation in laparoscopic transabdominal preperitoneal repair (TAPP) of inguinal hernia

Public title

Fixation or non-fixation of mesh in laparoscopic inguinal hernia repair

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

No history of hernia repair surgery No history of laparotomy No strangulated or incarcerated hernia Were satisfied to participate in the study

Exclusion criteria:

Cancellation of the surgery for any reason Occurrence of unwanted complications during the surgery resulting in serious complications or death Non-referral of the patient in post-operative follow-up for any reasons Dissatisfaction to continue the collaboration in the present study

Age

From **18 years** old to **50 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **86**

Actual sample size reached: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

86 eligible patients were recruited to the study by easy non-randomization method. Then we randomly assigned patients to one of tow groups using simple randomization through random allocation software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were randomly assigned to one of the two groups before surgery and without themselves knowing their group, their group was recorded by the secretary and the surgeon was informed. After the surgery, the student who was unaware of the allocation of the groups, completed the post-operative pain and other complications and hernia relapse cheklists and delivered to the secretary.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Esfahan University of Medical Sciences

Street address

Isfahn University of Medical Sciences, Hezar jarib st, Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-10-25, 1396/08/03

Ethics committee reference number

IR.MUI.REC.1396.083

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**

Severity of pain

Timepoint

One day after surgery, when releasing the hospital, one and two weeks and one and 6 months after surgery

Method of measurement

VAS (Visual analogue scale)

2**Description**

Early and late complications

Timepoint

The first week after surgery and in two weeks, one month, and six months after surgery.

Method of measurement

Periodic Regular Examination

3**Description**

Hernia relapse
Timepoint
The first week after surgery and in two weeks, one month, and six months after surgery.
Method of measurement
Periodic Regular Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients with inguinal hernia undergo inguinal hernia repair using mesh by laparoscopic transabdominal preperitoneal repair technique and mesh was fixed using suture.

Category

Treatment - Surgery

2

Description

Intervention group: patients with inguinal hernia undergo inguinal hernia repair using mesh by laparoscopic transabdominal preperitoneal repair technique but mesh was not fixed.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital in Isfahan

Full name of responsible person

Zakaria Sherbou

Street address

Alzahra Hospital, Sofe St, Isfahan, Iran

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8174673461

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zakaria Sherbou

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Person responsible for updating data

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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

Data will be kept private.

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

Yes - There is 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

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Using data to complete studies

From where data/document is obtainable

Isfahan university of medical science, Dr Zakaria Sherbou

What processes are involved for a request to access data/document

After deliberation of researcher request and presentation
of adequate documents, it will be able to exhibit

Comments