Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Protocol summary

Study aim

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

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 prepritonal 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 requiering surgery undergo inguinal hernia repair using mesh by laparoscopic transabdominal prepritonal 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 prepritonal 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
Isfehan

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 prepritonal 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 prepritonal 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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farajzadegan@med.mui.ac.ir

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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Resident

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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
Useing data to complete studies

From where data/document is obtainable
Isfahan university of medical sience, Dr Zakaria Sherbou

What processes are involved for a request to access data/document
After delibration of researcher request and presentation of adequate documents,it will be able to exhibite

Comments