

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Hernia relapse rate, Pain rate, Early and late complications

#### 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

#### 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 two 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 checklists 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**

Isfahan 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

###### **City**

Isfahan

###### **Province**

Isfahan

###### **Postal code**

8174673461

###### **Phone**

+98 31 1668 5555

###### **Email**

alzahra@mui.ac.ir

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Ziba Farajzadegan

##### **Street address**

Isfahan University of Medical Sciences, Hezar jerib Avne

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##### **Postal code**

7346181746

##### **Phone**

+98 31 3668 0048

##### **Email**

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

###### **Street address**

Building of Prophet Azam, Shahid Reza Pakdel, Isfahan University of Medical Sciences, Hezar Jereb St.

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###### **Email**

Dr.zsharbu82@gmail.com

## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

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Esfahan University of Medical Sciences

**Full name of responsible person**

Zakaria Sherbou

**Position**

Resident

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Medical doctor

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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**