

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Randomised Clinical Trial on Postoperative Chronic Pain and Quality of Life following Laparoscopic Trans-Abdominal Preperitoneal (TAPP) Inguinal Hernia Surgery; a Comparison between Mesh Fixation Methods of Tacks, Vicryl Suture, and Non-fixation

#### Protocol summary

##### Study aim

Comparison of postoperative chronic pain and quality of life following laparoscopic TAPP inguinal hernia repair between three groups of mesh fixation: tacks, Vicryl suture, and non-fixation

##### Design

Controlled double-blinded randomised clinical trial in three parallel study groups : tacks (n = 60), Vicryl suture (n = 60), non-fixation (n=60)

##### Settings and conduct

The present study will be conducted in Alzahra Treatment and Educational Center, Isfahan, Iran. Within one week from the surgery, each patient will be visited and interviewed. Physical examination and preoperative assessments will be performed, and follow-up visits will be scheduled. Patients will be divided randomly into three study groups by using the table of random numbers. Two highly qualified and experienced surgeons will perform all surgical procedures. The investigators will collect the pre- and post-operation data while both patients and investigators do not have any knowledge of the patient's assigned study group. All of the postoperative complications will be evaluated and confirmed by a blinded surgeon.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18, diagnosis of uncomplicated primary uni/bilateral reducible inguinal hernia; eligible for elective laparoscopic hernia repair and general anaesthesia, ASA score of  $\leq 3$  Exclusion criteria: Complicated, incarcerated, strangulated, or recurrent hernia; following medical conditions: coagulopathy, immunosuppression, current anticoagulation treatment, current opioid or alcohol substance abuse, ongoing long term treatment with steroids and analgesics, ASA score  $> 3$ , and BMI  $\geq 35$

##### Intervention groups

Interventions performed in this study included three methods of mesh fixation during inguinal hernia repair: mesh fixation with tacks, mesh fixation with Vicryl suture, non-fixation of the mesh.

##### Main outcome variables

Chronic post-herniorrhaphy Inguinal Pain and quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200114046127N1**

Registration date: **2020-02-20, 1398/12/01**

Registration timing: **retrospective**

Last update: **2020-02-20, 1398/12/01**

Update count: **0**

##### Registration date

2020-02-20, 1398/12/01

##### Registrant information

##### Name

Sara Aghaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3777 0372

##### Email address

saraaghaei.nsr@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2017-04-21, 1396/02/01

**Expected recruitment end date**

2018-09-23, 1397/07/01

**Actual recruitment start date**

2017-06-07, 1396/03/17

**Actual recruitment end date**

2018-12-04, 1397/09/13

**Trial completion date**

2019-12-21, 1398/09/30

**Scientific title**

Randomised Clinical Trial on Postoperative Chronic Pain and Quality of Life following Laparoscopic Trans-Abdominal Preperitoneal (TAPP) Inguinal Hernia Surgery; a Comparison between Mesh Fixation Methods of Tacks, Vicryl Suture, and Non-fixation

**Public title**

Postoperative Chronic Pain and Quality of Life following Laparoscopic Trans-Abdominal Preperitoneal (TAPP) Inguinal Hernia Surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age over 18, with the diagnosis of uncomplicated primary uni/bilateral reducible inguinal or femoral hernia; Eligible for elective laparoscopic hernia repair and general anaesthesia, ASA (American Society of Anesthesiologists) score of  $\leq 3$ .

**Exclusion criteria:**

Patients with complicated, incarcerated, strangulated, or recurrent hernia; Following medical conditions: coagulopathy, immunosuppression, current anticoagulation treatment, current opioid or alcohol substance abuse, ongoing long term treatment with steroids and analgesics, ASA score  $> 3$ , and BMI  $\geq 35$ .

**Age**From **18 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyst

**Sample size**Target sample size: **189**Actual sample size reached: **180****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomisation by using the table of random numbers

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients, investigators, and data analyst did not have

any knowledge of the patient's assigned study group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In addition to the effective treatment of the medical condition subjected to the study, this trial attempts to improve the patients' quality of life and to reduce surgical complications.

**Secondary Ids**

empty

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

Research Ethics Committee of Isfahan University of Medical Sciences and Health Services

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2018-01-02, 1396/10/12

**Ethics committee reference number**

IR.MUI.REC.1396.3.710

**Health conditions studied****1****Description of health condition studied**

Unilateral Inguinal hernia

**ICD-10 code**

K40.90

**ICD-10 code description**

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

**2****Description of health condition studied**

Bilateral Inguinal hernia

**ICD-10 code**

K40.20

**ICD-10 code description**

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

**3****Description of health condition studied**

Chronic pain after herniotomy

**ICD-10 code**

G89.28

**ICD-10 code description**

Other chronic postprocedural pain

**Primary outcomes****1****Description**

Chronic post-herniorrhaphy inguinal pain

**Timepoint**

3, 6, and 12 months after surgery

**Method of measurement**

100 mm Visual Analogue Scale for assessment of pain intensity

**2****Description**

Post-herniorrhaphy quality of life

**Timepoint**

12 months after surgery

**Method of measurement**

The Medical Outcome Survey SF-36 questionnaire for quality of life evaluation

**Secondary outcomes****1****Description**

Acute postoperative inguinal pain

**Timepoint**

1 and 10 days after surgery

**Method of measurement**

100 mm Visual Analogue Scale for assessment of pain intensity

**2****Description**

Intraoperative complications

**Timepoint**

During surgery

**Method of measurement**

Intraoperative assessments by the surgeon

**3****Description**

Postoperative complications including surgical site infection, seroma and hematoma formation, orchitis, and neuralgia

**Timepoint**

1 and 10 days, 3, 6, and 12 months after surgery

**Method of measurement**

Interview with the patient; physical examination

**4****Description**

Duration of surgery

**Timepoint**

During surgery

**Method of measurement**

Timer

**5****Description**

Length of hospital stay

**Timepoint**

In the first week after surgery

**Method of measurement**

Recording duration of hospitalization

**6****Description**

Duration of analgesic use for the management of postoperative groin pain

**Timepoint**

1 and 10 days, 3, 6, and 12 months after surgery

**Method of measurement**

Interview with the patient

**7****Description**

Time of return to normal daily activities

**Timepoint**

1 and 10 days, 3, 6, and 12 months after surgery

**Method of measurement**

Interview with the patient

**8****Description**

Recurrence of hernia

**Timepoint**

1 and 10 days, 3, 6, and 12 months after surgery

**Method of measurement**

Interview with the patient; physical examination

**Intervention groups****1****Description**

Control group: Patients undergo general anaesthesia and surgery is performed in Trendelenburg position. Thirty minutes before surgery, one gram of cefazoline is injected intravenously. CO2 Insufflation is performed via an open technique of umbilical 11 mm port insertion. In unilateral repair, two 5 mm ports are installed in midclavicular lines. Insertion point on the ipsilateral side is 2 inches above and on the contralateral side 2 inches below the umbilical line. In bilateral repair, both 5 mm ports are located on the umbilical line. Peritoneal dissection is started at the inferior epigastric vessels site and extended medially to umbilical vessels fold and laterally to ASIS with a maximum size of 13 cm. In the case of direct hernia, the hernia sac is dissected and reduced. In indirect or femoral hernias, Para pubic

preperitoneal fat pad is dissected to visualise pubic ramus and cooper ligament. Retrovesical preperitoneal dissection allows for better and easier mesh covering. Internal ring is explored and sac is dissected. After dissection of the spermatic cord from parietal peritoneum, a monofilament propylene 10x15 cm mesh is inserted and embedded in the preperitoneal space. This kind of mesh allows visualisation of underlying tissues. Medially mesh is in contact with paravesical space and laterally with ASIS. In the first group, the mesh is fixed to the inguinal ligament and pubic tubercle with 3-4 tacks. The last step is reperitonealization over the mesh and peritoneal repair.

#### Category

Treatment - Surgery

### 2

#### Description

First intervention group: In the second group, the mesh is spread in the same space, but in the next step, the mesh is fixed with a 2-0 Vickryl suture to a point over the internal ring. Other steps of the operation are carried out the same as the control group.

#### Category

Treatment - Surgery

### 3

#### Description

Second intervention group: In the third group, the exact surgical technique as the control group is applied, except that after mesh placement, fixation is not performed.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra treatment and educational center

##### Full name of responsible person

Dr. Sara Aghaei

##### Street address

Sofeh Blvd.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

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##### Fax

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##### Email

alzahra@mui.ac.ir

##### Web page address

<http://alzahra.mui.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Vice-Chancellery for Research and Technology of Isfahan University of Medical Sciences

##### Street address

Hezar Jerib street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

۷۳۴۶۱-۸۱۷۴۶

##### Phone

+98 31 3668 5149

##### Email

research@mui.ac.ir

##### Web page address

<http://english.mui.ac.ir/content/vice-chancellery-research-and-technology>

#### 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

Dr. Sara Aghaei

##### Position

Medical intern

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Others

##### Street address

Hezar Jerib Street

##### City

Isfahan

##### Province

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saraaghaei.nsr@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Behrooz Kleidari

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General surgery specialist; advanced laparoscopic surgery fellowship

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Sara Aghaei

**Position**

Medical intern

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Others

**Street address**

Hezar Jerib Street

**City**

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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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable