

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 ≤ 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 ≥ 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 ≤ 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 ≥ 35 .

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample sizeTarget 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

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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

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Hezar Jerib street

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Isfahan

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Isfahan

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۷۳۴۶۱-۸۱۷۴۶

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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

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Hezar Jerib Street

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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

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Latest degree

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Other areas of specialty/work

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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