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 prallel 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)

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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.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

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
Isfehan
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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۷۳۴۶۱-۸۱۷۴۶

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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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Assistant professor

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General surgery specialist; advanced laparoscopic surgery fellowship

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Person responsible for updating data

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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