Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Clinical Outcomes of Laparoscopic Inguinal Hernia Surgery using the Preperitoneal Intra-Abdominal TAPP Method with and without Septal Defect Closure in Patients with Inguinal Hernia: A Randomized Controlled Clinical Trial

Protocol summary

Study aim
Comparison of clinical outcomes of laparoscopic inguinal hernia surgery using TAPP preperitoneal intra-abdominal method with and without closure of septal defect

Design
Randomised, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at https://www.sealedenvelope.com, 76 patients who need inguinal hernia surgery will be randomly assigned to two surgery groups: transabdominal preperitoneal method with mesh alone and transabdominal preperitoneal method with Prolene mesh combined with defect internal ring.

Settings and conduct
76 patients who need inguinal hernia surgery will be randomly assigned to two surgery groups: transabdominal preperitoneal method with mesh alone and transabdominal preperitoneal method with prolene mesh combined with internal ring defect surgery. The outcomes of the surgery will be evaluated. In this study, the patients undergoing surgery and the outcome assessor will be unaware of the surgical procedure.

Participants/Inclusion and exclusion criteria
Unilateral or Bilateral Hernia; American Society of Anesthesiologists Risk score (ASA class 1 or 2); No Symptoms of Peritonitis; No Previous Major Abdominal and Pelvic Surgery; No Contraindication General Anesthesia or laparoscopy; No Incarcerated Hernia; No Strangulated Hernia

Intervention groups
Intervention group 1: Transabdominal laparoscopic preperitoneal surgery method without defect closure. Intervention group 2: Transabdominal laparoscopic preperitoneal surgery method with defect closure

Main outcome variables
Occurrence of complications of Hematoma; Operation area infection; Seroma and Pain immediately after surgery; Returning to normal activities and hernia recurrence after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140310016917N10**
Registration date: **2024-06-11, 1403/03/22**
Registration timing: **prospective**

Last update: **2024-06-11, 1403/03/22**
Update count: **0**

Registration date
2024-06-11, 1403/03/22

Registrant information

Name
Ali Ashraf

Name of organization / entity
Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2025-03-19, 1403/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Clinical Outcomes of Laparoscopic Inguinal Hernia Surgery using the Preperitoneal Intra-Abdominal TAPP Method with and without Septal Defect Closure in Patients with Inguinal Hernia: A Randomized Controlled Clinical Trial

Public title
Comparison of the Clinical Outcomes of Laparoscopic Inguinal Hernia Surgery using the Preperitoneal Intra-Abdominal TAPP Method with and without Septal Defect Closure in Patients with Inguinal Hernia: A Randomized Controlled Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Unilateral or Bilateral Hernia American Society of Anesthesiologists Risk score (ASA class 1 or 2)
Exclusion criteria:
Symptoms of Peritonitis Previous Major Abdominal and Pelvic Surgery Contraindication General Anesthesia or laparoscopy Incarcerated Hernia Strangulated Hernia
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done from the website https://www.sealedenvelope.com. The randomization of this study will be by the blocked randomization method. Based on the list obtained from this website, each person will be randomly assigned to the control or intervention group using 4 random blocks with the number of 19 blocks in a ratio of 1:1. Using this method, each person is assigned one of the letters A or B to each group, and for randomization, the list of codes obtained from this website will be provided to the project researchers, and every patient with inguinal hernia who meets the conditions for entering the study , will be entered into the plan according to the assigned code.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients undergoing surgery will be unaware of which surgical procedure they will undergo, and the outcome assessor will also be unaware of which patient will undergo which procedure.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Guilan university of medical sciences
Street address
University Research and Technology Vice-Chancellor, Shahid Siyadati St., Namjo St.
City
Rasht
Province
Guilan
Postal code
41937-13194
Approval date
2024-04-24, 1403/02/05
Ethics committee reference number
IR.GUMS.REC.1403.018

Health conditions studied

1

Description of health condition studied
Hernia
ICD-10 code
K40.9
ICD-10 code description
Unilateral inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
Occurrence of complication of Hematoma
Timepoint
24 hours after the surgery
Method of measurement
Clinical examination

2

Description
Occurrence of complication of surgery site infection
Timepoint
One month after surgery
Method of measurement
Clinical examination

3

Description
Occurrence of complication of Seroma
Timepoint
One month to 6 months after surgery
Method of measurement
Clinical examination and ultrasound

4

Description
Acute postoperative pain
Timepoint
24 hours after the surgery
Method of measurement
Visual Analogue Scale

5

Description
Chronic pain after surgery
Timepoint
6 months after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Returning to normal activities
Timepoint
6 months after surgery
Method of measurement
Patient interview

2

Description
Hernia recurrence
Timepoint
6 months after surgery
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Transabdominal laparoscopic preperitoneal surgery method without defect closure
Category
Treatment - Surgery

2

Description
Control group:Transabdominal laparoscopic preperitoneal surgery method with defect closure
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina Hospital
Full name of responsible person
Moein Moghadam Ahmadi
Street address
Poursina Hospital, Parastar St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Moein Moghadam Ahmadi
Position
Assistant Professor
Latest degree
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General Surgery
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable