

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 0434

Email address

aliashraf@gums.ac.ir

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.

City

Rasht

Province

Guilan

Postal code

41937-13194

Phone

+98 13 3232 3970

Email

poursina@gums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Ramyar Farzan

Street address

University Research and Technology Vice-Chancellor,
Shahid Siyadati St., Namjo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Phone

+98 13 3333 5821

Email

research@gums.ac.ir

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

Specialist

Other areas of specialty/work

General Surgery

Street address

Poursina Hospital, Parastar St.

City

Rasht

Province

Guilan

Postal code

41937-13194

Phone

+98 13 3232 3971

Email

crdu_poursina@gums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Moein Moghadam Ahmadi

Position

Assistant Professor

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Person responsible for updating data**Contact****Name of organization / entity**

Rasht University of Medical Sciences

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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