

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 1321 0434

##### Email address

alishraf@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.

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+98 13 3232 3970

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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,  
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#### **Phone**

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#### **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

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

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**Full name of responsible person**

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**Position**

Assistant Professor

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**Email**

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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