Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Enhanced View-Totally Extra-peritoneal (eTEP) Technique for Repair of Inguinal Hernia after Radical Prostatectomy: A Clinical Trial

Protocol summary

Study aim

Evaluation of the outcomes of the Enhanced View-Totally Extra-peritoneal (eTEP) technique for repair of inguinal hernia after radical prostatectomy

Design

A controlled clinical trial with paralleled groups of intervention (eTEP) and control (TAPP), without blinding, non-randomized, phase 3, with a sample size of 15 in each group.

Settings and conduct

This Phase 3 clinical trial evaluates patients by a general surgeon (laparoscopic fellowship) who reviews their history and examines them. If an inguinal hernia is diagnosed after radical prostatectomy, its type and suitability for extended total extraperitoneal surgery are assessed. Eligible patients are enrolled. An equal number in the other group undergo transabdominal preperitoneal surgery. Patients are selected and categorized through census sampling, not randomly. The sample size is 15 per group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Inguinal hernia diagnosis, Informed written consent, eligibility for laparoscopic surgery, absence of contra-indication for laparoscopic surgery, Exclusion criteria: hematologic and severe comorbidities, psychological and cognitive disorders, and generalized infectious disease

Intervention groups

The intervention groups will be operated with the eTEP technique, and the control group will be operated with the Transabdominal Preperitoneal (TAPP) technique.

Main outcome variables

Patients will undergo an ultrasound examination the day after surgery to identify any hematomas, seromas, or potential mesh displacements. Pain levels will be assessed using the Visual Analog Scale (VAS). Follow-up will be conducted via a questionnaire, either in-person if necessary or otherwise by phone. The following outcomes will be evaluated: Pain severity, surgery complications, vascular injury, bladder injury, intestine injury, and duration to regain pre-surgical daily abilities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231029059895N1**
Registration date: **2025-03-14, 1403/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2025-03-14, 1403/12/24**
Update count: **0**

Registration date

2025-03-14, 1403/12/24

Registrant information

Name

Masoud Sayadishahraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 913 184 8098

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-04, 1403/10/15

Expected recruitment end date

2025-04-04, 1404/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Enhanced View-Totally Extra-peritoneal (eTEP) Technique for Repair of Inguinal Hernia after Radical Prostatectomy: A Clinical Trial

Public title
The Enhanced View-Totally Extra-peritoneal (eTEP) Technique for Repair of Inguinal Hernia after Radical Prostatectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Inguinal Hernia diagnosis with a history of radical prostatectomy
Exclusion criteria:
Patients eligibility to be laparscopic inguinal hernia repair surgery candidates.

Age
From **18 years** old

Gender
Male

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib St., Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2025-02-08, 1403/11/20
Ethics committee reference number
IR.MUI.MED.REC.1403.455

Health conditions studied

1

Description of health condition studied
Inguinal Hernia
ICD-10 code
K40
ICD-10 code description
inguinal hernia

Primary outcomes

1

Description
Grade of pain
Timepoint
2 hours, 1 day, at discharge, one month after surgery
Method of measurement
Visual Analogue Scale

2

Description
complications (Hematoma, seroma, Rehospitalization, Hernia recurrence), Vascular, bladder or, bowels injury
Timepoint
During or after surgery
Method of measurement
Surgeon's evaluations and reports

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patients in this group are operated with the eTEP technique, which is described as follows: A transverse incision is performed superior to the umbilicus, utilizing a transrectal approach on the left side. The posterior sheath of the rectus abdominis muscle is meticulously separated to gain access to the preperitoneal space. The carbon dioxide gas source is calibrated to achieve an intra-abdominal pressure (IAP) of 12 mmHg. Following this, a 10 mm optic trocar is introduced. The hernia sac is transferred into the preperitoneal space and repositioned laterally. The pubic bone and the inguinal ligament are subsequently isolated. A 12 × 15 cm mesh is secured in place using a stapler. The preperitoneal space is then evacuated, and the surgical wounds are sutured closed, followed by

bandaging.

Category

Treatment - Surgery

2

Description

Control group: Patients in this group are operated on with the TAPP technique. In Transabdominal Preperitoneal (TAPP) repair for inguinal hernia, the procedure begins with the patient under general anesthesia in a supine Trendelenburg position. A 10 mm infraumbilical trocar is inserted for the laparoscope, with two additional 5 mm working ports placed in the lower abdomen. A peritoneal incision is made above the hernia defect, and the peritoneal flap is dissected to expose the preperitoneal space. The hernia sac is carefully reduced, with indirect sacs fully dissected and direct sacs reduced. A synthetic mesh (typically 10x15 cm) is then placed in the preperitoneal space, covering the myopectineal orifice, and secured with tacks or fibrin glue if necessary. The peritoneal flap is closed using sutures or tacks to prevent mesh exposure to the bowel. Finally, trocar sites are closed, and the patient is awakened from anesthesia and monitored postoperatively for early complications.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra University Hospital
Full name of responsible person
Masoud Sayyadi
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2

Recruitment center

Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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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
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
Masoud Sayyadi Shahraki
Position
Associate Professor
Latest degree

Subspecialist

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information is available.

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
-

Under which criteria data/document could be used
-

From where data/document is obtainable
-

What processes are involved for a request to access data/document
-

Comments