Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Comparative Study of Mesh Fixation versus Non-Fixation in Patients Undergoing TAPP Hernia Repair

Protocol summary

Study aim
A Comparative Evaluation of Mesh Fixation versus Non-Fixation in Patients Undergoing Transabdominal Preperitoneal (TAPP) Hernia Repair at Sina Hospital (2023–2025)

Design
Patients were randomly allocated into two groups by the study consultant. They subsequently underwent laparoscopic hernia repair using either mesh fixation or non-fixation. Each group consisted of 42 patients.

Settings and conduct
Patients aged 18–70 years who presented to Sina Teaching Hospital were included in the study. Data were collected from patients' clinical records as well as through the use of a checklist during in-person follow-up visits at 2 weeks, 1 month, 3 months, and 1 year after surgery.

Participants/Inclusion and exclusion criteria
Patients aged 18–70 years with a primary diagnosis of inguinal hernia confirmed by preoperative ultrasonography and/or physical examination, with no history of cardiac disease and no previous hernia surgery.

Intervention groups
Patients were randomly assigned to one of two treatment groups using block randomization. Random allocation was performed using blocks of varying sizes, all of which were multiples of two. Initially, block sizes were randomly selected, and subsequently, one of the possible permutations ensuring equal group sizes was generated. After allocation, patients were assigned to Group A or Group B. Group A included patients who underwent TAPP hernia repair with mesh fixation, while Group B consisted of patients who underwent TAPP hernia repair without mesh fixation.

Main outcome variables
In laparoscopic TAPP hernia repair, proper use of mesh without fixation may reduce the risk of recurrence, as well as decrease patient-related costs and the time required to return to normal activities.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241011063328N1**
Registration date: **2026-02-04, 1404/11/15**
Registration timing: **retrospective**

Last update: **2026-02-04, 1404/11/15**
Update count: **0**

Registration date
2026-02-04, 1404/11/15

Registrant information
Name
ghazal noorani
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-12-05, 1403/09/15
Expected recruitment end date
2025-12-06, 1404/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
A Comparative Study of Mesh Fixation versus Non-Fixation in Patients Undergoing TAPP Hernia Repair

Public title
A Comparative Study of Mesh Fixation versus Non-Fixation in Patients Undergoing TAPP Hernia Repair

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of inguinal hernia Absence of heart disease No history of hernia surgery

Exclusion criteria:
Patients with a history of diabetes Patients with chronic infections Patients with heart problems

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were randomly allocated into two groups: mesh fixation and non-fixation. Randomization was performed by the study consultant surgeon, who was not involved in data collection or outcome assessment. The investigators were blinded to group allocation. Following the reviewer’s comment, to address this concern, patient allocation was conducted by an independent surgeon (the study consultant), as previously stated.

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 Tehran University of Medical Sciences

Street address
Qods ave, Keshavarz Blvd,Tehran

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2024-10-07, 1403/07/16

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1403.089

Health conditions studied

1

Description of health condition studied
Inguinal Hernia

ICD-10 code
K40

ICD-10 code description
An abdominal hernia with an external bulge in the groin region

Primary outcomes

1

Description
Recurrence

Timepoint
Two weeks, one month, three months and one year

Method of measurement
Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: with mesh fixation

Category
Treatment - Devices

2

Description
Control group: No fixation

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person

M taghi Talebian
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Hasan abad sq,Tehran
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Sponsors / Funding sources

1

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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
Tehran 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
Tehran University of Medical Sciences
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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available