

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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Name of organization / entity

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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	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
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	Health conditions studied <u>1</u> 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 <u>1</u> Description Recurrence Timepoint Two weeks, one month, three months and one year Method of measurement Questionnaire
	Secondary outcomes empty
	Intervention groups <u>1</u> Description Intervention group: with mesh fixation Category Treatment - Devices <u>2</u> Description Control group: No fixation Category Treatment - Devices
	Recruitment centers <u>1</u> Recruitment center Name of recruitment center Sina Hospital Full name of responsible person
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Tehran University of Medical Sciences Street address Qods ave, Keshavarz Blvd,Tehran	

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Sponsors / Funding sources

1

Sponsor

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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

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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