

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4494 1931

Email address

ghazalnourani@gmail.com

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
Street address
Hasan abad sq,Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
hosp_sina@sina.tums.ac.ir
Web page address
<https://sinahospital.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
M taghi Talebian
Street address
Qods ave, keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6634 8500
Email
hosp_sina@sina.tums.ac.ir
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
Full name of responsible person

Ghazal Noorani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Laleh ave, Ferdows Blvd , Tehran
City
Tehran
Province
Tehran
Postal code
1484933941
Phone
+98 21 4494 1931
Email
ghazalnourani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ghazal Noorani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
Laleh ave, Ferdows Blvd , Tehran
City
Tehran
Province
Tehran
Postal code
1484933941
Phone
+98 21 4494 1931
Email
ghazalnourani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ghazal Noorani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
No 22,South Laleh,Hejazi Blvd,Tehran

City

Tehran

Province

Tehran

Postal code

1484933941

Phone

+98 21 4494 1931

Fax**Email**

ghazalnourani@gmail.com

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