

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Investigating the effect of using a hernia truss after inguinal hernia surgery on the occurrence of complications caused by the operation compared with lack of using truss

Protocol summary

Study aim

the effect of using a truss after inguinal hernia surgery on the occurrence of postoperative complications including seroma, acute pain, hematoma and local infection.

Design

A quasi-experimental study with a control group, without blinding, without randomization

Settings and conduct

Sampling is done in Sina Hospital and patients are placed in study groups of their own choice.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All inguinal hernia patients are candidates for TAPP laparoscopic surgery with mesh implantation. Exclusion criteria: presence of other types of hernias in the groin or abdominal wall, significant anatomical disorders, suffering from diabetes and other diseases affecting wound healing, non-compliance of the patient with post-operative recommendations and non-referral for follow-up

Intervention groups

Intervention group: After surgery for inguinal hernia repair by laparoscopic trans-abdominal peri-peritoneal (TAPP) method and mesh implantation according to the routine of all the aforementioned surgical procedures, immediately after the patient is conscious and transferred to the ward (and before being out of bed), the hernia is closed for the patient and within 6 weeks from the date of the operation, the patient must have a hernia Control group: A control group is selected from patients who only receive routine treatment (including TAPP surgery and mesh implantation).

Main outcome variables

Seroma, acute pain, hematoma, local infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220530055031N2**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Seyed Amir Miratashi Yazdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6312 0000

Email address

amiratashi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30

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

Investigating the effect of using a hernia truss after inguinal hernia surgery on the occurrence of complications caused by the operation compared with lack of using truss

Public title

Truss after inguinal hernia surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All inguinal hernia patients are candidates for TAPP laparoscopic surgery with mesh implantation

Exclusion criteria:

The presence of other types of hernia in the groin or abdominal wall
Affective anatomical disorders
Suffering from diabetes and other diseases affecting wound healing
Failure of the patient to follow the post-operative recommendations
Failure to refer for follow-up

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 76

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 medical faculty of Tehran
University of Medical Sciences

Street address

Room 604, 6th floor, Tehran University of Medical
Sciences Central Building, Keshavarz Blvd., Qods St.
intersection

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2023-07-05, 1402/04/14

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.212

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

seroma

Timepoint

Post-operative visit, first week visit

Method of measurement

expert opinion

Secondary outcomes

1

Description

acute pain

Timepoint

Post-operative visit

Method of measurement

subjective by patient

2

Description

hematoma

Timepoint

Post-operative visit, first week visit

Method of measurement

expert opinion

3

Description

local infection

Timepoint

Post-operative visit, first week visit

Method of measurement

expert opinion

Intervention groups

1

Description

Intervention group: After surgery for inguinal hernia repair by laparoscopic trans-abdominal peri-peritoneal (TAPP) method and mesh insertion according to the routine of all the above-mentioned surgical procedures and while observing other routine care (including painkillers, dressings and antibiotics), immediately after the patient is conscious and transferred to the ward (and before being out of bed), the hernia is closed for the patient and within 6 weeks from the date of the operation, the hernia must be closed. have a strap Patients are discharged with advice not to lift more than 5 kg and follow up 24 hours, one week, three months, six months and one year later.

Category

Treatment - Devices

2

Description

Control group: A control group is selected from patients who only receive routine treatment (including TAPP surgery and mesh implantation). The control group and the subject group are matched in terms of gender, age, type of hernia (direct, indirect and pantone) and smoking.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina hospital

Full name of responsible person

Seyed Amir Miratashi

Street address

Sina Hospital, Imam Khomeini Ave.

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 66 3485 0010

Email

hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Research and Technology Vice-Chancellor, 6th floor, Central Organization of the University, Keshavarz Blvd., corner of Quds St.

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8163 3698

Email

vcr@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

Seyed Amir Miratashi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam khomeini ave. sina hospital

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 0000

Email

amiratahi@sina.tums.ac.ir

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed Amir Miratashi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam khomeini ave., sina hospital

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 0000

Email

amiratahi@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Seyed Amir Miratashi Yazdi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

Imam khomeini ave., sina hospital

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 0000

Email

amiratahi@sina.tums.ac.ir

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

No - There is not 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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The entire data will be shared after unidentifying people personal data

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to perform further research with the request from the scientific institute

From where data/document is obtainable

Dear applicants will be referred to Sina Hospital's scientific Center for access to Documents and Data or the applicant can email the project executor. the email address is available. (amiratahi@sina.tums.ac.ir)

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

After receiving the letter from the project executor, the applicant can refer to Sina Hospital Research Center and after the approval of the executor, the documents and data will be available to executor within a week or the applicant can email directly to project executor so the executor provide the information

Comments