Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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

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1136746911

Phone
+98 66 3485 0010

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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
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+98 21 8163 3698

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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

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Tehran

Province
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Person responsible for scientific

inquiries

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Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Seyed Amir Miratashi

Position
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Person responsible for updating data

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Email
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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. (amiratashi@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