Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluating the recurrence rate and adverse events of transversalis muscle fascia repair in total extraperitoneal repair (TEP) of inguinal hernia in Isfahan Al Zahra Hospital autom and winter of 1402: a double-blind clinical trial

Protocol summary

Study aim

The aim of this study is to evaluate direct repair of hernia defects with sutures, with the aim of reducing seroma formation and recurrence after direct laparoscopic inguinal hernia repair.

Design

60 patients with direct inguinal hernia who meet the inclusion criteria, will be randomized in blocks based on whether the hernia is unilateral or bilateral with a one-to-one ratio by random allocation software to two groups of laparoscopic repair with TEP with or without repair of the inguinal canal with non-absorbable sutures.

Settings and conduct

The hernia will be repaired and then the main researcher of the study (surgeon) will provide the code and the patient's information to another researcher who intends to follow up the patient in the mentioned time intervals, who will not know the patients' surgical procedure.

Participants/Inclusion and exclusion criteria

Age older than 18 years, no history of open abdominal surgery, primary direct hernia or unilateral or bilateral recurrent hernia, no history of mesh implantation, BMI less than or equal to 40, and exclusion criteria: history of liver disorder characterized by ascites, failure kidney, failure to complete written consent, need to repair inguinal hernia with open surgery, history of abdominal surgery below the umbilical line Exclusion criteria: strangulated inguinal hernia

Intervention groups

Inguinal canal will be repair with the TEP method and the mesh will be inserted without fixation. In the intervention group, in addition to the above cases, after the complete reduction of the direct hernia sac, the fascia of the transversalis muscle around the direct hernia will be closed with a 3-0 non-absorbable thread.

Main outcome variables

The rate of surgical complications, including seroma, recurrence, surgical infection, acute pain, chronic pain, and other possible complications and patient safety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180312039067N2**
Registration date: **2024-02-29, 1402/12/10**
Registration timing: **prospective**

Last update: **2024-02-29, 1402/12/10**
Update count: **0**

Registration date

2024-02-29, 1402/12/10

Registrant information

Name

masoud sayadi shahraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3667 1832

Email address

sayadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the recurrence rate and adverse events of transversalis muscle fascia repair in total extraperitoneal repair (TEP) of inguinal hernia in Isfahan Al Zahra Hospital autom and winter of 1402: a double-blind clinical trial

Public title
Evaluating the recurrence rate and adverse events of transversalis muscle fascia repair in total extraperitoneal repair (TEP) of inguinal hernia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No history of abdominal surgery below the umbilical line Primary direct hernia or unilateral or bilateral recurrent hernia No history of mesh implantation BMI less than or equal to 40 No history of liver disorder characterized by ascites No history of renal failure failure to complete written consent
Exclusion criteria:
Need to repair inguinal hernia with open surgery Strangulated inguinal hernia
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
60 patients with direct inguinal hernia who meet the inclusion criteria will be randomized in blocks based on unilateral or bilateral hernia with a one-to-one ratio by random allocation software 2.0 into two groups of laparoscopic repair with TEP method with or without inguinal canal repair.
Blinding (investigator's opinion)
Double blinded
Blinding description
The main researcher of the study (surgeon) will provide the sealed code and the patient's information to another researcher who intends to follow up the patient in the mentioned time slots, who will not know about the patient's surgical method.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics comitte of Isfahan university of Medical Sciences
Street address
Hezar jarib street, Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2023-07-26, 1402/05/04
Ethics committee reference number
IR.MUI.MED.REC.1402.255

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
Operation time
Timepoint
First randomization day
Method of measurement
STOPWATCH

2

Description
Hospitalization time
Timepoint
First randomization day
Method of measurement
Documentation in medical records

Secondary outcomes

1

Description
Recurrence
Timepoint
Post operation 7th day, 1st, 3rd and 6th months
Method of measurement
Clinical exam

2

Description
Pain
Timepoint
Post operation 7th day, 1st, 3rd and 6th months
Method of measurement
Visual Analogue Scale (VAS) measures pain intensity

3

Description
Seroma
Timepoint
Post operation 7th day, 1st, 3rd and 6th months
Method of measurement
Ultrasonography

4

Description
Infection
Timepoint
Post operation 7th day, 1st, 3rd and 6th months
Method of measurement
Clinical exam

5

Description
Analgesics
Timepoint
Post operation 7th day, 1st, 3rd and 6th months
Method of measurement
History taking

Intervention groups

1

Description
Control group: The inguinal canal will be repaired with the TEP method based on the published guidelines, and the mesh will be inserted without fixation.
Category
Treatment - Surgery

2

Description
Intervention group: In addition to the above cases, after the complete reduction of the direct hernia sac, the fascia of the transversalis muscle around the direct hernia will be closed with a 3-0 non-absorbable thread.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra university hospital
Full name of responsible person
Masoud Sayadi
Street address
Alzahra university hospital, sofe Blvd.
City
Isfehan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
sayadi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
Street address
Isfahan university of medical sciences, vice chancellor of research
City
Isfehan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
research@mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Pedram Hadipour
Position
Non-faculty specialist doctor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Number5, Mahan Convened, West aban alley, Kharazmi avenue, Sepahanshahr, Isfahan, Iran
City
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Province
Isfehan
Postal code
6816744111
Phone
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Email
pmhr۶۸@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Masoud Sayadi
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Number5, Mahan convened, West aban alley, Kharazmi avenue, Sepahanshahr, Isfahan, Iran
City
Isfehan
Province
Isfehan
Postal code
6816744111
Phone
+98 31 3651 8499
Email
sayadi@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Vahid Reisi-Vanani
Position
Non-faculty Medical doctor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
No 3, Ally 87, Taleghani crossroad, Shahrekord, Iran
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817673131
Phone
+98 38 3224 4633
Email
vahidreisi@outlook.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be 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
To share the data and documents of this research, only the information related to the main outcome will be shared. Also, files that can be published and do not violate people's privacy will be published
When the data will become available and for how long
The access period will start 6 months after the results are published
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
If there are conditions, all our data will be shared except

personal information of people. The use of our data will only be allowed for similar research and review of our data by other researchers. All those who work in universities and scientific centers and decide to conduct similar research or check the accuracy of our data can access our data.

From where data/document is obtainable

In order to receive information, all eligible people can collect data by referring to the person in charge of the project. The contact methods are the email address vahidreisi@outlook.com or the contact number 09136043590

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

To receive information after sending the request, the requests will be reviewed within 10 days. If the above conditions are met, the information will be sent to the provided email within 30 days at most.

Comments