

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

Isfahan

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.

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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

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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

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,
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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

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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

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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