

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation and comparison of the results of hernioplasty treatment by Totally Extraperitoneal (TEP) technique by spinal anesthesia and general anesthesia

Protocol summary

Study aim

Evaluation and comparison of the results of hernioplasty treatment by Totally Extraperitoneal (TEP) technique by spinal anesthesia and general anesthesia

Design

Clinical trial without control group with parallel, randomized, phase 3 groups on 110 patients A random number table was used for randomization.

Settings and conduct

This study is performed in Al-Zahra Hospital in Isfahan. Patients are randomly divided into two groups. The first group undergoes hernioplasty under spinal anesthesia and the second group undergoes general anesthesia surgery. Pain and complications of surgery are measured and compared between the two groups 1 hour, 3 hours and 6 hours after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of inguinal hernia, patients between 50-60 years, patients with no spinal anesthesia or general anesthesia and laparoscopic surgery, obtaining written consent. Exclusion criteria: Patients who have not referred for follow-up treatment for any reason, Patients who for any reason do not want to continue to cooperate in this project, have a history of cardiovascular disease, history of major abdominal surgery, history of any cancer, defect Safety

Intervention groups

Intervention group 1: Patients in this group undergo TEP hernioplasty by spinal anesthesia. 1 hour, 3 hours and 6 hours after surgery, patients' pain and the duration of surgery and surgical complications in them will be measured and compared. Intervention group 2: Patients in this group undergo TEP hernioplasty by general anesthesia. 1 hour, 3 hours and 6 hours after surgery, patients' pain and the duration of surgery and surgical complications in them will be measured and compared.

Main outcome variables

Pain and complications of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N6**

Registration date: **2020-12-14, 1399/09/24**

Registration timing: **prospective**

Last update: **2020-12-14, 1399/09/24**

Update count: **0**

Registration date

2020-12-14, 1399/09/24

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 1582

Email address

rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-01-25, 1399/11/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the results of hernioplasty treatment by Totally Extraperitoneal (TEP) technique by spinal anesthesia and general anesthesia

Public title

Evaluation and comparison of the results of hernioplasty treatment by spinal anesthesia and general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of inguinal hernia Patients between 50-60 years Patients should not be contraindicated for spinal anesthesia or general anesthesia and laparoscopic surgery. Obtaining written consent

Exclusion criteria:

Patients who have not sought follow-up treatment for any reason Patients who for any reason do not want to continue to cooperate in this project History of cardiovascular disease History of major abdominal surgery History of any cancer Immunodeficiency

Age

From **50 years** old to **65 years** old

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization, table of random numbers. In this study, reading the table of predefined random numbers (eg, up or down) and the researcher's second default is to consider even numbers for intervention group . The researcher begins to read the numbers in a predetermined manner and the patients are divided.

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 Esfahan university of Medical sciences

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

City

Isfahan

Province

Isfahan

Postal code

۸۱۳۷۸۶۶۵۱۵

Approval date

2019-05-11, 1398/02/21

Ethics committee reference number

IR.MUI.MED.REC.1398.066

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**

Pain

Timepoint

1 hour, 3 hours and 6 hours after surgery

Method of measurement

Visual Analogue Scale questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1: Patients in this group undergo TEP hernioplasty by spinal anesthesia. 1 hour, 3 hours and 6 hours after surgery, patients' pain and the duration of surgery and surgical complications in them will be measured and compared.

Category

Treatment - Surgery

2**Description**

Intervention group 2: Patients in this group undergo TEP hernioplasty by general anesthesia. 1 hour, 3 hours and 6 hours after surgery, patients' pain and the duration of surgery and surgical complications in them will be

measured and compared.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Masoud Sayadi

Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Isfahan

Province

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8174673461

Phone

+98 31 3668 0042

Email

parsa.alinezhad85@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

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haghjoo.sh@med.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

Masoud Sayadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments