Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Isfehan

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

City

Isfahan

Province

Isfehan

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8174673461

Phone

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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