

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparative evaluation of different-doses fentanyl effects on epidural block quality in patients undergoing elective inguinal hernia surgery

Protocol summary

Summary

The purpose of this study is comparison effect of different doses of fentanyl on epidural block quality and complications. In this randomized, double blind clinical trial, a number of sixty patients between thirty to seventy years old enrolled in study. Inclusion criteria: candidate for elective inguinal hernia surgery; lack of severe systemic and mental disease; consent to take part in the study and exclusion criteria: history of drug allergy; opiate use; sedative use. Three groups A, B and C were selected. These groups were unified based on age and sex. The group A received block with Epinephrine and Lidocaine, groups B and C except for same amount of Epinephrine and Lidocaine, orderly received 25µg and 50µg Fentanyl. In each group patients evaluate for hemodynamic variable, block quality and analgesic needs. Then data's record and statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502171617N10**
Registration date: **2015-05-13, 1394/02/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-13, 1394/02/23

Registrant information

Name

Mansour Choubsaz

Name of organization / entity

Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 83 1724 6708

Email address

mchoubsaz@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2015-07-20, 1394/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of different-doses fentanyl effects on epidural block quality in patients undergoing elective inguinal hernia surgery

Public title

different-doses fentanyl effects on epidural block quality in hernioraphy surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidate for elective hernioraphy surgery; lack of severe systemic and mental disease; consent to participate in the study Exclusion criteria: history of drug allergy; opiate use; sedative use

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

6718938179

Approval date

2014-07-22, 1393/04/31

Ethics committee reference number

17181

Health conditions studied

1

Description of health condition studied

inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

Inguinal hernia (unilateral) NOS

Primary outcomes

1

Description

Pain

Timepoint

0,1,4 hours

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Block level

Timepoint

0,1,4 hours

Method of measurement

Dermatom

Intervention groups

1

Description

Adding 25 micro gram fentanyl to lidocaine and epinephrine

Category

Treatment - Drugs

2

Description

adding 50 micro gram fentanyl to lidocaine and epinephrine

Category

Treatment - Drugs

3

Description

lidocaine and epinephrine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr.Hosein Karim

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Imam Reza Hospital

Full name of responsible person

Fatemeh Aalinezhad

Position

Resident of Anesthesiology

Other areas of specialty/work

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khosro farhadi

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty