Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Bupivacaine local anesthetic effect on after inguinal hernia pain relief

Protocol summary

Summary

This is a double-blinded clinical trial conducted on patients who needed inguinal hernia surgery. We recruited patients over 10 and all recurrent, strangulated, sliding, or gangrene hernias were excluded from study. After Ethical committee approval, 80 patients were allocated into 2 groups using block-randomized and also informed consent were taken. Using interview, demographic data was collected. Bupivacaine 0.5 Mg / kg diluted in 5 ml normal saline injected subcutaneously in intervention group. The placebo group received only 5 cc of normal saline. Within 24 hours and 48 hours after surgery patients pain measured using visual analogue scale in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101304808N3**
Registration date: **2011-04-30, 1390/02/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-04-30, 1390/02/10

Registrant information

Name

Mozhdeh Zarei

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1613 1278

Email address

mozh.zarei@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdestan University of Medical Science

Expected recruitment start date

2008-07-22, 1387/05/01

Expected recruitment end date

2009-03-21, 1388/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Bupivacaine local anesthetic effect on after inguinal hernia pain relief

Public title

Local anesthesia on pain after surgery

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: patients who require Inguinal hernia surgery; Age over 10 years exclusion criteria: recurrence of hernia; sliding hernia strangulation - gangrene complications

Age

From **11 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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
Kurdistan University of Medical Sciences
Street address
sanandaj Kurdistan University of Medical Sciences
City
sanandaj
Postal code
66117713446
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
24/4/87 3755 ع14پ

Health conditions studied

1

Description of health condition studied
pain after inguinal hernia surgery
ICD-10 code
k40
ICD-10 code description
Inguinal hernia

Primary outcomes

1

Description
pain after inguinal hernia surgery
Timepoint
0,24, and 48 hours later
Method of measurement
visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
intervention: bupivacain 0.5 Mg / kg add to normal saline 5 ml was subcutaneous injection.
Category
Treatment - Drugs

2

Description
control: only 5 cc of normal saline was injected.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kurdistan University of Medical Sciences
Full name of responsible person
Mozhdeh Zarei
Street address
Pasdaran Blvd, Kurdistan University of Medical Sciences, Sanandaj
City
Sanandaj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kurdistan university of Medical Science
Full name of responsible person
Fardin Gharibi
Street address
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City
Sanandaj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kurdistan university of Medical Science
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

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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