

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effects of adding tramadol to Bupivacaine on postoperative pain in inguinal hernia surgery

Protocol summary

Summary

In this study, Patients randomly are divided into three groups & gotten general anesthesia with similar methods and medications (10micg sufentanil - 1 mg Midazolam - atracurium, isoflurane inhalation 0.6%). In group I: Bupivacaine0.25%(8 ml) + 2 ml normal saline is injected subfacial into external oblique muscle at the end of surgery . In group II: Bupivacaine0.25%(8 ml) + tramadol(100 mg =2cc) is injected similarly. . In group III: Bupivacaine0.25%(8 ml) + 2 ml normal saline is injected subfacial into external oblique muscle at the end of surgery AND, 15 minute after end of surgery , Tramadol 100 mg is injected intramuscular also. Surgery is done by the same surgeon & technique. Then at 2, 4, 8, 12 hours after the end of surgery when hematoma or inflammation of the surgical site be ruled out, the severity of pain is checked at rest, coughing and moving states (during switching) by VAS. Also, the first analgesic request time , the total analgesic intake . level of consciousness and frequency of nausea and vomiting will be recorded. Level of consciousness is based on 3 point scale I

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010194938N2**
Registration date: **2011-05-30, 1390/03/09**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-30, 1390/03/09

Registrant information

Name

HOSSEIN FARZAM

Name of organization / entity

KERMANSHAH UNIVERSITY OF MEDICAL SCIENCES

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Science

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2011-07-27, 1390/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of adding tramadol to Bupivacaine on postoperative pain in inguinal hernia surgery

Public title

Effect of adding tramadol to Bupivacaine on postoperative pain.

Purpose

Treatment

Inclusion/Exclusion criteria

In this study, the candidates for open-elective unilateral inguinal herniorrhaphy with age between 12 & 75 are enrolled if been satisfied. Patients with ASA class more than II, have hernia recurrence, drug addiction, patients

with DM (diabetes mellitus), patients who have hypersensitivity to anesthetic drugs and who develop postoperative inflammation or hematoma of surgical site are excluded.

Age

From **12 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Medical ethics committee of Kermanshah university of Medical Sciences

Street address

Shahid beheshti ave

City

Kermanshah

Postal code

Approval date

2010-06-15, 1389/03/25

Ethics committee reference number

7536

Health conditions studied

1

Description of health condition studied

inguinal hernia

ICD-10 code

k40-9

ICD-10 code description

Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

Pain intensity

Timepoint

2, 4, 8, 12 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Level of consciousness

Timepoint

2,4,8,12

Method of measurement

3 point scale

2

Description

The 1st analgesic request

Timepoint

2,4,8,12

Method of measurement

time report

3

Description

Total analgesic intake

Timepoint

2,4,8,12

Method of measurement

mg

4

Description

Nausea & Vomiting

Timepoint

2,4,8,12

Method of measurement

Observation & Question

Intervention groups

1

Description

Group 1 ; After general anesthesia (sufentanil 10 mcg, midazolam 1 mg , isoflurane 0.6% , atracurium) 8 ml bupivacaine 0.25% + 2ml normal saline is injected subcutaneous in external oblique muscle at the end of surgery by surgeon.

Category

Treatment - Other

2

Description

After general anesthesia (sufentanil 10 mcg ,midazolam 1 mg , isoflurane 0.6% , atracurium) 8 ml bupivacaine 0.25% + 2ml =100mg tramadol is injected subfacial in external oblique muscle at the end of surgery by surgeon.

Category

Treatment - Other

3

Description

After general anesthesia (sufentanil 10 mcg, midazolam 1 mg , isoflurane 0.6% , atracurium) 8 ml bupivacaine 0.25% + 2ml normal saline is injected subfacial in external oblique muscle at the end of surgery by surgeon. Tramadol 100mg is injected also intramuscularly , 15 minutes after surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah University of Medical Sciences, Imam Reza Hospital.

Full name of responsible person

Hosein Farzam

Street address

Kermanshah University of Medical Sciences, Imam Reza Hospital. Department of anesthesiology.

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Kermanshah University of Medical Sciences

Full name of responsible person

Farid Najafi

Street address

67188, Shahid Beheshti, Boulevard, Kermanshah, Iran,

City

kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research 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

Kermanshah university of medical sciences

Full name of responsible person

Hossein Farzam

Position

Assistant prof

Other areas of specialty/work

Street address

4 floor-number, 18-116 alley-nobahar ave

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hfarzam@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

kermanshah university of medicine student

Full name of responsible person

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Position

assistant prof.

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Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

HOSSIEN FARZAM

Position

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

Web page address

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