

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The effect of adding Dexamethasone to Bupivacaine in ilioinguinal and iliohypogastric nerves block on pain after inguinal hernia surgery with spinal anesthesia

Protocol summary

Summary

The aim of this study is the effect of adding Dexamethasone to Bupivacaine in ilioinguinal and iliohypogastric nerves block on pain after inguinal hernia surgery with spinal anesthesia. Study is a randomized interventional study on 44 patients aged from 20 to 80 years old who candidate for elective unilateral inguinal hernia surgery with American Society of Anesthesia (ASA) class I and II. Individuals with history of opioid addiction, analgesic consumption, surgery time more than 1 hour and half being spinal anesthesia off during surgery will be excluded. Patients will be randomly divided into two groups (n=22) on the basis of selection of colored cards. All patients will be underwent spinal anesthesia with similar method. At the end of surgery, all patients will be underwent ilioinguinal and iliohypogastric block with direct injection of medicine around nerves tissues. Patients in control group will be received 2 cc Bupivacaine 0.5% plus 1 cc normal saline and in case group, 2 cc Bupivacaine 0.5% plus 1 cc (4 mg) Dexamethasone. Surgeon and anesthesiology resident will do not inform about kinds of drugs. The postoperative pain will be recorded at 1, 2, 4, 12 and 24 hours after surgery on the basis of visual analog scale. Analgesia requirements and first time of feeling pain after surgery will be recorded. Additional analgesics (intravenous pethidine 50 mg or Diclofenac suppository 100 mg) will be administered to the patients based on visual analog scale in the postoperative period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012425676N6**

Registration date: **2017-02-19, 1395/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-19, 1395/12/01

Registrant information

Name

Hamid Kayalha

Name of organization / entity

Qazvin University of Medical Sciences & Health Services

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 Qazvin University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding Dexamethasone to Bupivacaine in ilioinguinal and iliohypogastric nerves block on pain after inguinal hernia surgery with spinal anesthesia

Public title

The effect of adding Dexamethasone to Bupivacaine in ilioinguinal and iliohypogastric nerves block on pain after inguinal hernia surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 20 to 45 years; candidate for elective unilateral inguinal hernia surgery; ASA class 1 or 2. Exclusion criteria: The reluctance of patients; opioid addiction; analgesic consumption during the past 24 hours; surgery time more than 1 hour and half; being spinal anesthesia off during surgery; patients needing mesh to repair and having both ilioinguinal & iliohypogastric nerves injury during surgery.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This study is double-blinded. Anesthesiology resident and patients do not inform about kinds of drugs. Random sampling is on the basis of selection of colored cards by patients.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of the Qazvin University of Medical Sciences

Street address

Shahid Bahonar Blvd, Qazvin.

City

Qazvin

Postal code

3419759811

Approval date

2011-07-06, 1390/04/15

Ethics committee reference number

12059/20/28

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

Timepoint

At 1, 2, 4, 12 and 24 hours after surgery

Method of measurement

Score of Pain according to visual analog scale

2**Description**

Amount of analgesic consumption

Timepoint

At 1, 2, 4, 12 and 24 hours after surgery

Method of measurement

Total dose of administered pethidine or Diclofenac

3**Description**

First time of feeling pain

Timepoint

At 1, 2, 4, 12 and 24 hours after surgery

Method of measurement

Patient file

Secondary outcomes

empty

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

At the end of surgery, all patients will be underwent ilioinguinal and iliohypogastric block and, 2 cc Bupivacaine 0.5% plus 1 cc (4 mg) Dexamethasone directly will be injected around nerves tissues.

Category

Prevention

2**Description**

At the end of surgery, all patients will be underwent ilioinguinal and iliohypogastric block and 2 cc Bupivacaine 0.5% plus 1 cc normal saline directly will be injected around nerves tissues.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Velayat Educational and Treatment Center

Full name of responsible person

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Street address

Minoodar, 22 Bahman Blvd, Qazvin.

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2**Recruitment center****Name of recruitment center**

Rajaii Educational and Treatment Center

Full name of responsible person

Dr Hamid Kayalha

Street address

Rajee Hospital, Padegan Avenu, Qzvin.

City

Qazvin

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Taghi Naserpour

Street address

Shahid Bahonar Blvd, Qazvin

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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 of Qazvin 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**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Hamid Kayalha

Position

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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