

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness of adding Dexamethasone to epidural Bupivacaine on the onset of anesthesia and duration of perioperative analgesia in unilateral inguinal herniorrhaphy.

Protocol summary

Summary

We will compare onset of action and duration of analgesia of bupivacaine with and without dexamethasone in epidural anesthesia in this double blind randomized clinical trial study. 44 patients, aged 30-70 years, candidates for unilateral inguinal herniorrhaphy will be selected, randomly. Patients with any contraindication to perform epidural anesthesia or corticosteroid administration will be excluded. The 44 patients will be divided in two groups of 22 each. In group A, an epidural anesthesia will be done with 18 ml of bupivacaine 0.5% and 8 mg of dexamethasone (2 ml) and in group B, the epidural anesthesia will be done with the same amount of bupivacaine and 2 ml of sterile water, preoperatively. The onset of anesthesia, duration of analgesia, nausea and vomiting in the first hour, and pain intensity in the two groups will be compared and any complications of the procedure will be noted.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012062910137N1**
Registration date: **2012-07-21, 1391/04/31**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-21, 1391/04/31

Registrant information

Name

Nabiollah Heydarian

Name of organization / entity

Kasahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-03-21, 1392/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of adding Dexamethasone to epidural Bupivacaine on the onset of anesthesia and duration of perioperative analgesia in unilateral inguinal herniorrhaphy.

Public title

Effect of Dexamethasone in epidural anesthesia with Bupivacaine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 30-70 years; ASA class I-II; Candidates for unilateral inguinal herniorrhaphy.
Exclusion criteria: Complicated inguinal hernia (Incarcerated, strangulated and so on); History of peptic ulcer disease; Any contraindication for epidural

anesthesia (back fusion, coagulopathy, local infection, inability to give appropriate position); Failure to achieve epidural analgesia; Obese and diabetic patients, and patients who had received corticosteroids or immunosuppressive drugs in the last 6 months, or if they had contraindication to corticosteroids; Any contraindication for corticosteroid administration; Patient refusal for epidural anesthesia.

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: **44**

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**

Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, 5th km,
Ghotbe Ravand Bulv.

City

Kashan

Postal code**Approval date**

2012-05-31, 1391/03/11

Ethics committee reference number

1139/1/5/29/پ

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**

Onset of anesthesia

Timepoint

Every 30 seconds, after intervention

Method of measurement

Pinprick test

2**Description**

Duration of analgesia

Timepoint

Every 1 minute, after intervention

Method of measurement

Pain perception by the patient

3**Description**

Pain intensity

Timepoint

Just after starting pain

Method of measurement

Visual analogue scale

Secondary outcomes**1****Description**

Nausea

Timepoint

In 1st hour after intervention

Method of measurement

Patient observation

2**Description**

Vomiting

Timepoint

In 1st hour after intervention

Method of measurement

Patient observation

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

Dexamethasone 8 mg, epidural injection, single dose.

Category

Treatment - Drugs

2

Description

Sterile water, 2 ml, Epidural injection, single dose

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Nabiollah Heydarian (Anesthesia resident)

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr. Gholam Ali Hamidi (Vice chancellor for research)

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Nabiollah Heydarian

Position

Anesthesia resident

Other areas of specialty/work

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Board of anesthesiology

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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