

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 36 1543 0402

##### Email address

drheydarian@kaums.ac.ir

##### 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 (beck 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

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

##### City

Kashan

## 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)

##### Street address

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

##### City

Kashan

##### 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

#### Street address

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

#### City

Kashan

#### Postal code

#### Phone

+98 36 1555 2999

#### Fax

+98 36 1557 5057

#### Email

drheydarian@yahoo.com

#### Web page address

<http://www.kaums.ac.ir/>

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Seyed Mohammad Reza Razavizadeh

##### Position

Board of anesthesiology

##### Other areas of specialty/work

##### Street address

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

##### City

Kashan

##### Postal code

##### Phone

+98 36 1555 2999

##### Fax

+98 36 1557 5057

##### Email

mr\_razavi48@yahoo.com

##### Web page address

<http://www.kaums.ac.ir/>

## Person responsible for updating data

#### 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

##### Street address

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

##### City

Kashan

##### Postal code

##### Phone

+98 36 1555 2999

**Fax**

+98 36 1557 5057

**Email**

drheydarian@yahoo.com

**Web page address**

<http://www.kaums.ac.ir/>

**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*