

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### A Comparative study of effects of epidural Methylprednisolone Asetate(Depo-Medrol) Injection on pain relief of patient with disc hernia of lumbar spine, with and without spinal canal stenosis

#### Protocol summary

##### Summary

The aim of this study is to compare the effect of epidural steroid injection on pain relief in patients with disc hernia of lumbar spine, with and without spinal canal stenosis in MRI. 50 patients with history of chronic lumbar pain will be put into two groups in parallel fashion based on having evidence of disc hernia in lumbar spine with (25 cases) or without spinal canal stenosis (25 cases). 80 Mg Methylprednisolone Asetate(Depo-Medrol) is injected to epidural space in lumbar region(L3-L5) for all two group patients. For access and identification of epidural space one of the two method of hanging drop, or loss of resistance is used. Injection will be done in scrubby operating room. Pain will be measured and recorded in two ways ,Visual Analog Scale, and Verbal Rating Pain Score , at 5 times: prior to injection; 48 hours; a week; one month and two months after the injection . Two groups of patients will be compared in relation to consumption of analgesic drugs too.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138809251766N2**

Registration date: **2010-02-16, 1388/11/27**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2010-02-16, 1388/11/27

##### Registrant information

###### Name

Karim Nasserri

###### Name of organization / entity

Kurdistan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Kurdistan University of Medical Sciences

###### Expected recruitment start date

2009-05-01, 1388/02/11

###### Expected recruitment end date

2010-05-01, 1389/02/11

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

A Comparative study of effects of epidural Methylprednisolone Asetate(Depo-Medrol) Injection on pain relief of patient with disc hernia of lumbar spine, with and without spinal canal stenosis

###### Public title

Study the effect of injection of steroids to lumbar region on pain relief

###### Purpose

Supportive

###### Inclusion/Exclusion criteria

Inclusion criteria's: history of lumbar pain that radicated to lower limb and continued for more than 6 month, history of intervertebral disc herniation with, or without spinal stenosis confirmed with MRI ,ASA class 1

or 2, ability to sign informed consents. Exclusion criteria: age under 18, age above 60, neurologic deficit (such as paresis or plegia of limbs), past medical history of surgery on spinal canal, history of dependency or addiction to opioids

#### **Age**

From **18 years** old to **60 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **50**

#### **Randomization (investigator's opinion)**

Not randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Kurdistan university medical sciences ethics committee

##### **Street address**

Pasdaran street

##### **City**

Sanandaj

##### **Postal code**

##### **Approval date**

2009-11-27, 1388/09/06

##### **Ethics committee reference number**

p14p8017-clause-6

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Lumbar and other intervertebral disc disorders with radiculopathy

#### **ICD-10 code**

M51.1+

#### **ICD-10 code description**

Lumbar and other intervertebral disc disorders with radiculopathy

## **Primary outcomes**

### 1

#### **Description**

Pain relief

#### **Timepoint**

48 hrs, 1 week, 2 week, 1 month and 2 months later

#### **Method of measurement**

Visual Analogue Scale (VAS) and Verbal pain Rating scale

## **Secondary outcomes**

### 1

#### **Description**

Using analgesic

#### **Timepoint**

During 2 month

#### **Method of measurement**

the amount, kind and dosage (mg) of analgesic that used for pain relief

## **Intervention groups**

### 1

#### **Description**

Injection a single doses of 80 Mg Methylprednisolone Asetete (Depo-Medrol) to lumbar epidural space (L3-L5) via a disposable 16G needle

#### **Category**

*empty*

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Beasat hospital

##### **Full name of responsible person**

Karim nasseri

##### **Street address**

Keshavarze street

##### **City**

Sanandaj

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for research, Kurdistan University of Medical Sciences

##### **Full name of responsible person**

Ataolah Haidari

##### **Street address**

Pasdaran Street

##### **City**

Sanandaj

**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, Kurdistan 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**

Kurdistan University of Medical Sciences

**Full name of responsible person**

Karim Nasser

**Position**

Anesthetist / Assistant Professor

**Other areas of specialty/work**

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Kurdistan University of Medical Sciences, Faculty of Nursing

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Shoaleh Shami

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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*