Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Name of organization / entity

Kurdistan University of Medical Sciences

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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 radiculated 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 opioides

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
Ataaolah 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

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Position

Anesthetist / Assistant Professor

Other areas of specialty/work

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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