

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The Comparative study of Effect of caudal & Lumbar Approach in epidural steroides injection in the treatment of acute radicular Low back pain.

Protocol summary

Summary

The aim of this study is to compare caudal and lumbar approach in epidural steroids injection for treatment of acute radicular Low back pain. In a randomized clinical trial, 32 patients with radicular low back pain, aged 20-50 years, and confirmed L5-S1 disk herniation that indicated for non surgical treatment were enrolled and assigned into lumbar or caudal group. Drugs are the same in both group consisting triamsinolon 40 mg, lidocaine 50 mg, and normal saline 10 ml, total volume of 13 ml. In lumbar group, the patients received single injection at L5-S1 space in sitting position but in caudal group, they received an injection at sacral hiatus in lateral position. 30 minute after injection, maximum leg raising was measured and pain intensity was measured 30 min, 1 week, and 1 month after the injection based on the visual analogue scale. Patient's satisfaction and any possible complication such as headache were recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138801181617N2**

Registration date: **2010-06-14, 1389/03/24**

Registration timing: **na**

Last update:

Update count: **0**

Registration date

2010-06-14, 1389/03/24

Registrant information

Name

Mansour Choubsaz

Name of organization / entity

Imam Reza Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

دانشگاه علوم پزشکی و خدمات بهداشتی درمانی کرمانشاه

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2010-01-21, 1388/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparative study of Effect of caudal & Lumbar Approach in epidural steroides injection in the treatment of acute radicular Low back pain.

Public title

The Comparative study of Effect of caudal & Lumbar Approach in epidural steroides injection in the treatment of acute radicular Low back pain: a randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: radicular low back pain, age 20-50 years, confirmed L5-S1 disk herniation, indication for non surgical treatment Exclusion criteria: bleeding disorders, anticoagulant therapy, local infections, septicemia, hypovolemia, pregnancy, ankylosing spondylitis, low back pain more than 12 month duration, previous spinal surgery, untreated tuberculosis, addiction, spinal tumors,

multiple sclerosis, history of diabetes, ASA more than II, unwilling to participate

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

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**

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

Postal code**Approval date**

empty

Ethics committee reference number

742028315

Health conditions studied**1****Description of health condition studied**

Radiculopathy

ICD-10 code

M54.1

ICD-10 code description

Neuritis or radiculitis

Primary outcomes**1****Description**

intensity of pain

Timepoint

30 min, 1 week, and 1 month later

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

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

Triamsinolon 40 mg, lidocaine 50 mg, and normal saline 10 ml, total volume of 13 ml, single injection at L5-S1 space in sitting position

Category

Treatment - Drugs

2**Description**

Triamsinolon 40 mg, lidocaine 50 mg, and normal saline 10 ml, total volume of 13 ml, single injection at sacral hiatus in lateral position

Category

Treatment - Drugs

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Habiballah khazaie

Street address

Pro-Vice-chancellor for research, Kermanshah University of Medical Sciences

City

kermanshah

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

Pro-Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Pro-Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

City

Kermanshah

Grant name**Grant code / Reference number**

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Pro-Vice-chancellor for research, Kermanshah University of Medical Sciences and Health Services

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

Imam Reza Hospital

Full name of responsible person

Seid Said Hashemi

Position

Resident of Anesthesiology

Other areas of specialty/work

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Position

Anesthesiologist/Assistant Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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