Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 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 spondilitis, low back pain more than 12 month duration, previous spinal surgery, untreated tubercolosis, 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
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Full name of responsible person
Seid Said Hashemi
Position
Resident of Anesthesiology
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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