Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of the effects and complications of transforaminal Triamcinolone and Dexmedetomidine in radicular low back pain.

Protocol summary

Summary

Objectives: Chronic radicular Low Back Pain is One of The Most Common Cause of Pain Clinic Admission Which is treated with Epidural Transforaminal Steroid Injection. Due to Steroid Injection Side Effects, We Decided to Compare Dexmedetomidine Effect in This Study. Study design (study participation – sample size), Exclusion and inclusion criteria: Sample size is 30 patients. Patients with chronic low back pain which fulfill study criteria, randomly assigned into two groups by block randomization. The study will be done double – blinded. Intervention: Patients under local anesthesia and fluoroscopic guidance in operative room, transforaminal epidural block will be done. In group 1, Ropivacaine 0.2%, 3cc with Triamcinolone 20 mg and in group 2, Ropivacaine 0.2% ,3cc with Dexmedetomidine 1 microgram per kilogram will be injected. Visual analog scale, ODI, analgesic need, SLR (straight leg raise) will be checked as follow: before injection, 2 weeks later first, 3 and 6 month later. FBS will be checked and Recorded as follow: before injection, 2 weeks later and first month later. Ca, Mg, Vit.C and Vit.D will be checked and Recorded as follow: before and 1 month later. The results will be analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201312037984N12**
Registration date: **2017-09-15, 1396/06/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-09-15, 1396/06/24

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Iran University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effects and complications of transforaminal Triamcinolone and Dexmedetomidine in radicular low back pain.

Public title

A comparison of the effects and complications of transforaminal Triamcinolone and Dexmedetomidine in radicular low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Age 20-70 years; Pain that has not

responded to treatment for at least 6 weeks; Evidence of Nerve root involvement as disc bulging and/or foraminal stenosis in CT/MRI; VAS > 4; ASA class I, II; Patients' Informed consent Exclusion criteria: Patients with coagulopathy ; Infection in injection site as Herpetic diseases; Anatomical and congenital spine deformity as severe scoliosis; Surgical history instrument insertion; Psychological severe disorders; History of harmful reaction to local anesthetic and steroid; Patients with motor deficit or progressive neural defect; Cancer ; Neural foramen radiological access difficulty; Substance abuse; HIV; Acute trauma; Cauda Equina syndrome; More than 3 level abnormalities ;. Absence of radicular pain

Age
From **20 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
This study is double blinded. Patients and evaluators had no information about drug of injection.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences.

Street address
Iran university of medical science, Hemmat highway,Tehran

City
Tehran

Postal code
1445613131

Approval date
2017-05-22, 1396/03/01

Ethics committee reference number
IR.IUMS.FMD.REC 1396.30894

Health conditions studied

1

Description of health condition studied
chronic low back pain

ICD-10 code
G54.8

ICD-10 code description
low back pain

Primary outcomes

1

Description
low back pain

Timepoint
Before injection,two weeks,1,3 and 6 month after intervention

Method of measurement
pain score measured with visual analogue scale in Questionnaire.

Secondary outcomes

1

Description
Oswestry Disability Index questionnaire (ODI) and straight leg raising test (SLR), complications

Timepoint
Before injection, two weeks, 1,3 and 6 moth after intervention.

Method of measurement
Questionnaire

Intervention groups

1

Description
In intervention group 3 ml 0.2% Ropivacaine (Ropivacaina Molteni, Molteni, Italy) plus Dexmedetomidine 1 microgram per Kilogram (Precedex, Hospira, USA) was injected in the selected level by a curved blunt tip 10 cm needle (Cosman, USA) under fluoroscopic guidance via transforaminal epidural approach.

Category
Treatment - Drugs

2

Description
In control group 3 ml 0.2% Ropivacaine (Ropivacaina Molteni, Molteni, Italy) plus 20 mg Triamcinolone (Triamcinolone acetonide, EXIR, IRAN) was injected in the selected level by a curved blunt tip 10 cm needle (Cosman, USA) under fluoroscopic guidance via transforaminal epidural approach.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Medical Center
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Iran University of Medical Sciences
Full name of responsible person
Dr Seyyed Ali Javad Mousavi
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Hemmat Expressway, Iran University of Medical Sciences
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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 and Technology of Iran 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
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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