Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A comparison of the efficacy of transforaminal Triamcinolone and Magnesium sulfate injection in chronic 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 Transforaminal Steroid Injection. Due to Steroid Injection Side Effects, We Decided to Compare Magnesium Sulfate Effects in This Study. Study design: 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 in one center. Participation: inclusion criteria: radicular pain at least for 6 weeks, MRI findings, VAS>4, age between 20 and 70 years. Exclusion criteria: coagulopathy, local and systematic infections, allergic reaction to drugs, pregnancy, more than 3 pathologic levels and severe scoliosis. Intervention: Patients under local anesthesia and fluoroscopic guidance in prone position in operative room, transforaminal block will be done. In group 1, Ropivacaine 0.2%, 3cc with Triamcinolone 20 mg and in group 2, Ropivacaine 0.2% ,3cc with Magnesium Sulfate 150 mg will be injected. Visual analog scale (VAS), Oswestry disability Index (ODI), analgesic need, straight leg raise (SLR) will be checked as follow: before injection, 2 weeks later first, 3 and 6 months later. Fasting Blood Sugar (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: **IRCT201306307984N10**
Registration date: **2017-11-12, 1396/08/21**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-11-12, 1396/08/21

Registrant information

Name
Farnad Imani
Name of organization / entity
Iran University of Medical Sciences
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Iran (Islamic Republic of)
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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 efficacy of transforaminal Triamcinolone and Magnesium sulfate injection in chronic low back pain.

Public title

A comparison of the efficacy of transforaminal Triamcinolone and Magnesium sulfate injection in chronic

low back pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Age 20-70 years 2. Pain at least 6 weeks 3. Evidence of Nerve root involvement as disc bulging and/or foraminal stenosis in CT/MRI 4. VAS > 4 5. ASA class I, II 6. Patients' Informed consent Exclusion criteria: 1. Patients' with coagulopathy 2. Infection in injection site as Herpetic diseases 3. Anatomical and congenital spine deformity as severe scoliosis 4. Surgical history instrument insertion 5. Psychological severe disorders 6. History of harmful reaction to local anesthetic and steroid. 7. Patients with motor deficit or progressive neural defect. 8. Cancer 9. Neural foramen radiological access difficulty 10. Substance abuse 11. HIV 12. Acute trauma 13. Cauda Equina syndrome 14. More than 3 level abnormalities 15. Absence of Inevitable radicular pain

Age

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

Gender

Both

Phase

N/A

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

2016-09-10, 1395/06/20

Ethics committee reference number

IR.IUMS.REC.1395.27279

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

Patient performance is based on Oswestry Disability Index, and degree of Leg Raising is based on Straight Leg Raising Test, and possible complications will be recorded.

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 150 mg Magnesium Sulfate (Magnesium sulfate 50%, SAMEN, 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

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

Dr Farnad Imani

Street address

Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

City

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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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Tehran

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

Name of organization / entity

Rasool Akram Medical Center

Full name of responsible person

Dr Farnad Imani

Position

Interventional pain fellowship, professor of anesthesiology

Other areas of specialty/work

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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