

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A comparison study of the effects of Triamcinolone and magnesium sulfate in caudal neuroplasty in chronic low back pain.

Protocol summary

Study aim

Comparative study of the effect of triamcinolone and magnesium sulfate in caudal neuroplasty in chronic low back pain

Design

A double blind, randomized clinical trial with control group; community based and pragmatic; with parallel group design; phase3

Settings and conduct

This study is carried out at the Rassoul Akram Therapeutic Complex. Fifty patients with lumbar radiculopathy were randomly divided into two groups. In both groups, drugs are injectable and the injection site of the drug in the patient's body is in same area. Therefore, patients are not aware of the type of the drug. Also, the outcome evaluator is unaware of the random allocation. In the first group, triamcinolone (80 mg), and in the 2nd group, magnesium (50 mg) was injected into the caudal space. In the 2nd day, the same drug with half dose of the first day was injected via a catheter. The evaluation criteria included physical examinations, pain scale, Disability Index, analgesic consumption before, 2 weeks, and 1, 3, and 6 months later; blood glucose before procedure, 2nd day, and two weeks later; HgA1C before, 3 and 6 months later; and MRI before and 6 months later.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Chronic low back pain; Moderate to severe pain score; Age 40-70 years; Inadequate response to conservative treatment; Disc protrusion. Exclusion criteria: Severe canal stenosis; Sequestered disc; Sever spinal deformity;tumors;fracture); infection; Drug reaction; Sever psychological disorders; Pregnancy and lactation; Severe or sudden neurological deficit; Patient's dissatisfaction to participate the study.

Intervention groups

Intervention group1: receiving triamcinilone Intervention group2: receiving ropivacaine Control group: receiving magnesium sulfate and ropivacaine

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111102007984N29**

Registration date: **2019-02-05, 1397/11/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-05, 1397/11/16**

Update count: **0**

Registration date

2019-02-05, 1397/11/16

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6651 5758

Email address

farnadimani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison study of the effects of Triamcinolone and magnesium sulfate in caudal neuroplasty in chronic low back pain.

Public title

A comparison of the effects of Triamcinolone and magnesium sulfate in caudal neuroplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Chronic low back pain more than six months +/- radiculopathy Moderate to severe pain score (> 3, based on the Visual Analog Scale) Being at the age of 40-70 years Inadequate response to conservative and physiotherapy treatments after three months American Anesthesiologists Classification (ASA) I-II Disc protrusion in MRI

Exclusion criteria:

Severe canal stenosis (more than two thirds in axial MRI view) Sequestered disc (fragmented) Decreased disc height more than 60% Sever spinal deformity Spinal tumors Vertebral fracture Spondylolisthesis Grade>2 Local or systemic infection Taking anticoagulants Drug abuse History of drug reaction Sever psychological disorders Pregnancy and lactation Severe or sudden neurological deficit such as urinary or fecal incontinence Body Mass Index (BMI) > 35 Patient's refusal Diabetes mellitus MRI contraindications (cardiac pacemaker, defibrillator, aortic aneurysm clips) Impossible prone positioning

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

By using the randomize number table, the patients were divided into two equal groups (n=25).

Blinding (investigator's opinion)

Double blinded

Blinding description

Both drugs are injectable and the injection site of both drugs in the patients' body is in the same area.

Therefore, patients are not aware of the type of drug.

Also, the outcome evaluator is unaware of the random allocation.

Placebo

Not used

Assignment

Parallel

Other design features**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 Sciences, Hemmat Expressway corner

City

Tehran

Province

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Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2018-07-24, 1397/05/02

Ethics committee reference number

IR.IUMS.REC.1397.297

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

low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

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

low back pain

Timepoint

Before injection,two weeks,1,3 and 6 months after intervention

Method of measurement

pain score measured with visual analogue scale in Questionnaire.

Secondary outcomes**1****Description**

Functional disability Index

Timepoint

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

Method of measurement

Oswestry Disability Index questionnaire (ODI)

2

Description

Raising straight leg, raising straight leg reversely

Timepoint

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

Method of measurement

straight leg raising test (SLR) ,Reverse straight leg raising test (RSLR)

3

Description

Bonnet

Timepoint

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

Method of measurement

Questionnaire

4

Description

FABER

Timepoint

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

Method of measurement

Questionnaire

5

Description

Gaenslen

Timepoint

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

Method of measurement

Questionnaire

6

Description

Tiptoe and Heel walking

Timepoint

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

Method of measurement

Questionnaire

7

Description

Visual Analogue Pain scale

Timepoint

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

Method of measurement

Questionnaire

8

Description

Analgesic consumption

Timepoint

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

Method of measurement

Questionnaire

9

Description

blood sugar

Timepoint

Blood sugar ,before injection,2 th day and 2th week after injection

Method of measurement

The result of the tests

10

Description

HbA1C

Timepoint

injectionHbA1C, before injection,3 and 6 month after injection

Method of measurement

The result of the tests

11

Description

Spinal canal diameter changes at MRI

Timepoint

MRI, before injection and 6 month after injection

Method of measurement

MRI report

Intervention groups

1

Description

In intervention group 10 ml Ropivacaine 0.2% (produced by Molteni, Italy) ,10 cc Nacl 5%(produced by Samen, Iran) ,50 mg Magnesium sulfate (produced by Shahid Ghazi,Iran) and 1500 unit Hyalase(produced by Darupakhsh,Iran)was injected in the caudal epidural space by a Racz catheter (produced by Epimed,USA) under fluoroscopic guidance .

Category

Treatment - Drugs

2

Description

Control group: In control group 10 ml Ropivacaine 0.2% (produced by Molteni, Italy) ,10 cc Nacl 5%(produced by Samen,Iran) ,80 mg Triamcinolone (produced by

Caspian, IRAN) and 1500 unit Hyalase(produced by Darupakhsh,Iran)was injected in the caudal epidural space by a Raciz catheter (produced by Epimed,USA) under fluoroscopic guidance .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat- Rasul Akram Medical Coplex

Full name of responsible person

Farnad Imani

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Anesthesiology and pain department of Hazrat-Rasoul Medical Complex, Niayesh street, Sattar-Khan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Farnad Imani

Position

Interventional pain fellowship, professor of anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Some part of the clinical information of the patients will be shared

When the data will become available and for how long

6 months after the end of the project

To whom data/document is available

Faculty Members of Medical Sciences Universities

Under which criteria data/document could be used

For further studies

From where data/document is obtainable

Deputy of Research & Technology Pain Research Center, Iran University of Medical Sciences

What processes are involved for a request to access data/document

First, at the request of the university, she/he will be informed at the request of the university's deputy of the research department, and then she/he will be referred to the research center during the administrative process and the data will be received by the committee of the research center of the center with a commitment and acceptance.

Comments