

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the effect of epidural steroid injection with mixture of steroid and calcitonin in lumbosacral canal stenosis patients.

Protocol summary

Study aim

Comparing the effect of epidural steroid injection with mixture of steroid and calcitonin in lumbosacral canal stenosis patients.

Design

Thirty four patients with history of low back pain originating from lumbar canal stenosis are selected. They didn't respond to conservative management for 6 months and are randomly(block randomization) divided to two groups: one group receives 80 mg methyl prednisolon and 4 cc marcaine via epidural under fluoroscopic guide while second group receives 80 mg methyl prednisolon , 4 cc marcaine and 100 units calcitonin plus recommendation for life style modification and exercise for two groups. On weeks 0,2,4 and 8 all patients complete the VAS, OSWESTRY AND QUEBEC questionnaires.

Settings and conduct

Chamran hospital , Shiraz, Fars , Iran Study will be double blind. Patients and outcome assessors will not be informed about type of injected drugs.

Participants/Inclusion and exclusion criteria

Inclusion criteria: complete and sign the informed consent form , pain and other symptoms of lumbosacral spinal stenosis don't respond to conservative management for 6 months, age between 45 to 75
Exclusion criteria: 1.Simultaneous radiculopathy 2.Diabetes mellitus 3.Rheumatologic disease such as collagen vascular disease , SLE , gout 4.Simultaneous neuropathy 5.Brucella infection 6.BMI> 42 7.Knee arthroplasty in affected side 8.Coagulopathy 9.Allergy to medication 10.Hepatic , renal or cardiac failure 11.Cancer 12.Pregnancy 13.Inability to complete questionnaire and poor cooperation

Intervention groups

Group A receives 80 mg methyl prednisolon and 4 cc marcaine via epidural under fluoroscopic guide while group B receives 80 mg methyl prednisolon , 4 cc Marcaine and 100 units Calcitonin plus recommendation

for life style modification and exercise for two groups.

Main outcome variables

pain reduction , functional improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171112037419N1**

Registration date: **2017-12-26, 1396/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2017-12-26, 1396/10/05**

Update count: **0**

Registration date

2017-12-26, 1396/10/05

Registrant information

Name

Razieh pirzad

Name of organization / entity

Shiraz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 32319040

Email address

am_ebrpoor@me.iut.ac.ir

Recruitment status

Recruitment complete

Funding source

vice chancellor of research in Shiraz university of medical sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of epidural steroid injection with mixture of steroid and calcitonin in lumbosacral canal stenosis patients.

Public title

Injection for lumbar canal stenosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Lumbar pain nonresponsive to conservative management for 6 months Between 45-75 y/o
Completing and signing informed consent form

Exclusion criteria:

Diabetes Mellitus Rheumatoid arthritis, collagen vascular disease, gout, lupus Simultaneous lumbar radiculopathy or neuropathy Brucella infection BMI>42 Knee or hip arthroplasty Bleeding tendencies and disorders Impaired cognition Drug allergy Liver, renal, pulmonary or cardiac problem Pregnancy Cancer

AgeFrom **45 years** old to **75 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **34****Randomization (investigator's opinion)**

Randomized

Randomization description

Block randomization Randomization unit: individual by statistical software A list with even block height is provided and the secretor divides the patient according to the list.

Blinding (investigator's opinion)

Double blinded

Blinding description

patients and researcher dont know about type of injected drugs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Shiraz university of medical sciences

Street address

Zand avenue, Shiraz university of medical sciences building.

City

Shiraz

Province

Fars

Postal code

14336 - 71348

Approval date

2017-11-07, 1396/08/16

Ethics committee reference number

IR.SUMS.MED.REC.1396.92

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

lumbosacral spinal stenosis

ICD-10 code

M48.06

ICD-10 code description

SPINAL STENOSIS , LUMBAR REGION

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

pain

Timepoint

2 months

Method of measurement

VAS, OSWESTRY, Quebec questionnaires

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

functional class and quality of life
improvement, decreased oral medication consumption

Timepoint

2 months

Method of measurement

VAS, OSWESTRY, QUEBEC questionnaires

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

control group: 80 mg methyl prednisolon and 4 cc

marcaine epidural injection plus education of life style modification and exercise

Category

Treatment - Drugs

2

Description

intervention group:80 mg methyl prednisolon , 4 cc marcaine and 100 units calcitonin epidural injection plus education of life style modification and exercise

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Chamran hospital

Full name of responsible person

Hamid Reza Farpour

Street address

Central building of Shiraz University of Medical Sciences, Zand Street

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Hamid Reza Farpour

Position

Associated professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Latest degree

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Full name of responsible person

Razie pirzad

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physical medicine and rehabilitation student

Latest degree

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Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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