

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison between the effect of calcitonin by mesotherapy versus steroid epidural injection in spinal canal stenosis

Protocol summary

Study aim

Comparison of the effect of calcitonin injection in the form of mesotherapy with epidural steroid injection in patients with spinal cord stenosis

Design

In this study, 20 patients with lumbar spinal stenosis who had the conditions for entering the study were randomly divided into two groups of 10, the first group was calcitonin by mesotherapy and the second group was epidural steroid injection.

Settings and conduct

This is a double-blind, randomized clinical trial that will be conducted on referrals to physical medicine and rehabilitation clinics of Shiraz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Persons aged 40 to 75 who are able to complete questionnaires Diabetes mellitus, rheumatic diseases, collagen and vascular disease, gout. Lupus, nerve damage, neuropathies and brucella BMI >42 History of trauma and spinal fractures and spondylolisthesis, History of injections inside or around a joint bleeding disorders History of allergy and allergic reaction to used drugs History of significant liver, kidney and cardiac disorders Use of anticoagulants

Intervention groups

The first group of calcitonin was injected with mesotherapy. The second group of steroids was injected epidural.

Main outcome variables

Reduce the need for epidural injections and reduce the side effects of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171201037696N1**

Registration date: **2018-01-14, 1396/10/24**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-14, 1396/10/24**

Update count: **0**

Registration date

2018-01-14, 1396/10/24

Registrant information

Name

Elham Sheibani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3824 5055

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a_sheibani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-16, 1396/09/25

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of calcitonin by mesotherapy versus steroid epidural injection in spinal canal stenosis

Public title

calcitonin mesotherapy in spinal canal stenosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain and other clinical symptoms of lumbar canal stenosis Complete and sign the consent form Age between 40 and 75 years

Exclusion criteria:

Diabetes mellitus, rheumatic diseases, collagen and vascular disease, gout. Lupus, nerve damage, neuropathies and brucella BMI >42 History of trauma and spinal fractures and spondylolisthesis, History of injections inside or around a joint bleeding disorders History of allergy and allergic reaction to used drugs History of significant liver, kidney and cardiac disorders Use of anticoagulants

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized blocked method

Blinding (investigator's opinion)

Single blinded

Blinding description

A single blind trials that the patient and the investigator are aware of how the study is conducted, but the statistical analyzer is kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Fars Province, Shiraz, Zand

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2017-10-16, 1396/07/24

Ethics committee reference number

IR.SUMS.MED.REC.1396.70

Health conditions studied

1

Description of health condition studied

spinal canal stenosis

ICD-10 code

M48.06

ICD-10 code description

Spinal stenosis, lumbar region

Primary outcomes

1

Description

Reducing pain after undergoing mesotherapy

Timepoint

Before starting treatment and 4 and 8 weeks after injection

Method of measurement

Visual Analogue Scale Questionnaire

Secondary outcomes

1

Description

Evaluation the effect of calcitonin mesotherapy and epidural steroid on functional improvement

Timepoint

Before starting treatment and 4 and 8 weeks after injection

Method of measurement

Oswestry Disability Index Questionnaire. Quebec Back pain Disability index

Intervention groups

1

Description

Intervention group: Injection of calcitonin by mesotherapy

Category

Treatment - Drugs

2

Description

Intervention group: epidural steroid injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Physical Medicine and Rehabilitation of Shiraz University of Medical Sciences

Full name of responsible person

Hamidreza Farpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seied Basir Hashemi

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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 Farpoor

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham sheibani

Position

Resident

Latest degree

Medical doctor

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