Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating effects of Acupuncture versus Mesotherapy with Calcitonin in Patients with Lumbar Spinal Canal stenosis(randomized controlled clinical trial)

Protocol summary

Study aim
Study of the effect of acupuncture and calcitonin mesotherapy compared to the control group (exercise therapy) in patients with lumbar spinal stenosis

Design
Randomized clinical trial with control group,parallel-group,double-blind,60patients

Settings and conduct
Calcitonin injections:3sessions, 1session/week.Acupuncture:10sessions, at a frequency of 3sessions/week. evaluated before treatment, and then again at 4 and 8 weeks after the intervention through clinical visits and standardized questionnaires. The study site:Imam Reza Clinic. clinical supervisor and the outcome assessor will be blinded

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age40_75 years;Completion of the consent form;Confirmation of diagnosis of lumbar spinal canal stenosis through radiography,MRI,or electromyography;At least 6 months of lumbar spinal canal stenosis symptoms(low back pain,claudication,radicular pain in the lower limbs.) Exclusion Criteria: Pregnancy;breastfeeding;systemic or localized infection;Uncontrolled DM;Rheumatoid,collagen vascular diseases,cancer;severe liver,kidney,heart,or respiratory diseases;bleeding disorders;use of anticoagulant drugs;Brucellosis;spinal canal surgery;diabetic neuropathy or radiculopathy;BMI>42 allergic reaction to drug used in the study;Inability to complete the questionnaire;acupuncture or calcitonin injection in the last 3months;symptoms of cauda equina syndrome(perineal numbness, urinary or fecal incontinence);Muscle weakness with MMT less than 4/5

Intervention groups
A)Mesotherapy with Calcitonin & Therapeutic exercise B)Acupuncture & Therapeutic exercise C)Therapeutic exercise

Main outcome variables
Pain intensity;Functional performance;Weight-bearing ability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250511065690N1**
Registration date: **2025-06-12, 1404/03/22**
Registration timing: **prospective**

Last update: **2025-06-12, 1404/03/22**
Update count: **0**

Registration date
2025-06-12, 1404/03/22

Registrant information

Name
Nazanin Rashidi rezvan

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-23, 1404/06/01

Expected recruitment end date
2026-08-23, 1405/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating effects of Acupuncture versus Mesotherapy with Calcitonin in Patients with Lumbar Spinal Canal stenosis(randomized controlled clinical trial)

Public title
Effects of Acupuncture in lumbar spinal canal stenosis ; Effects of Mesotherapy with calcitonin in lumbar spinal canal stenosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 40-75 years old confirmation of the diagnosis of lumbar spinal canal stenosis by radiography, MRI, or Electrodiagnosis study. ATleast 6 months should have passed since the onset of symptoms of lumbar spinal canal stenosis (such as low back pain, claudication, radicular leg pain, etc.)
Exclusion criteria:
pregnancy breastfeeding critical systemic or local infection uncontrolled diabetes Rheumatic and collagen vascular diseases cancer history of severe hepatic, renal, cardiac, or pulmonary disease bleeding disorders use of anticoagulants Brucellosis history of spinal canal surgery Diabetic neuropathy Concurrent radiculopathy BMI over 42 history of allergic reaction to the drug used in the study presence of cauda equina syndrome symptoms(perineal numbness, urinary and fecal incontinence) muscle weakness with manual muscle test score less than 4 out of 5 inability to communicate and complete the questionnaire history of acupuncture or calcitonin injection in thepast three months
Age
From **40 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the random allocation method will be 6-block randomization, as follows: Group A represents individuals receiving the intervention of mesotherapy with calcitonin and therapeutic exercise. Group B represents individuals receiving acupuncture and therapeutic exercise. Group C represents individuals receiving therapeutic exercise only. Next, using a random number table and assigning numbers from 0 to 9 to each possible permutation, a randomized list of 60 participants will be generated. This list will include 10 blocks of 6 participants each (6*10 = 60 total participants), and the allocation of each method to each participant will be determined. Each participant's group allocation will be assigned through the sealed envelope method, and the analyst will be blinded to the group assignments to prevent bias in the analysis.
Blinding (investigator's opinion)
Double blinded
Blinding description
To ensure concealment, the random sequence method is placed in sealed envelopes in the possession of another person who is unaware of the research process, and the questionnaires are completed by an individual unaware of the group assignment. Clinical caregiver: We train the person who is responsible for the care and follow-up of patients on how to complete the questionnaire. This person has no knowledge of the type of intervention the patient received. Outcome assessor: The completed questionnaires are given to a person who is unaware of the interventions performed and is asked to determine the degree of pain reduction and increase in function and weight-bearing ability and balance in each individual, according to the questionnaire.
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
Shiraz Medical School, Imam Hossein Square, Zand Street, Shiraz
City
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Fars
Postal code
7134845794
Approval date
2025-04-22, 1404/02/02
Ethics committee reference number
IR.SUMS.MED.REC.1404.071

Health conditions studied

1

Description of health condition studied

LUMBAR SPINAL CANAL STENOSIS

ICD-10 code

M48.06

ICD-10 code description

Spinal stenosis, lumbar region

Primary outcomes

1

Description

Pain Intensity

Timepoint

Before treatment, 4 and 8 weeks after start treatment

Method of measurement

VAS(Visual)analoge scale

2

Description

function

Timepoint

Before treatment, 4 and 8 weeks after start treatment

Method of measurement

health Shortform_(survey(SF_36 Quebec scale(QBPDS disability pain(back

3

Description

Ability to hop on one leg for 5 steps

Timepoint

Before treatment, 4 and 8 weeks after start treatment

Method of measurement

hopping standard scale (SHS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A)mesotherapy with calcitonine and exercises in the form of three injection sessions (two 50-unit ampoules of calcitonin + 4 cc of 2% lidocaine per session) with an interval of one week. Using sterile disposable 10cc syringes with a 12mm*0.27mm needle and one cc injection at each point. Calcitonin and lidocaine manufacturer: Caspian Tamin

Category

Treatment - Drugs

2

Description

Intervention group: B)acupuncture and exercise For acupuncture, 25 x 25 needles are inserted bilaterally at BL-23, BL-25, BL-26, BL-37, BL-40, BL-54, BL-57, LI-4, BL-60, DU-3, DU-4 to a depth of 2.5 cm in the muscles, and DU-20 is inserted intradermally and remains in the patient's body for 30 minutes / Acupuncture needle manufacturer: Huanqiu

Category

Treatment - Other

3

Description

Control group: (c) Exercise therapy . Therapeutic exercises include isometric gluteal muscle exercises, hamstring and calf muscle stretching, and knee bending to the chest. The duration of each exercise is 15 to 30 seconds and is repeated 30 time per day.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Clinic

Full name of responsible person

Nazanin Rashidirezvan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Nazanin Rashidirezvan

Position

assistant

Latest degree

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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