

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of pulsed electromagnetic field on pain intensity and function of patients with spinal stenosis compared to the control group referring to physical medicine clinics: A randomized controlled clinical trial study

Protocol summary

Study aim

Determining the effect of pulsed electromagnetic fields on pain intensity and function in patients with spinal stenosis compared to a control group referring to physical medicine clinics

Design

A clinical trial with intervention and control groups, with factorial groups, single-blind, randomized on 60 patients, using computer-generated random number sequences for randomization.

Settings and conduct

This is a clinical trial study that will be conducted on patients with lumbar canal stenosis who refer to Isfahan physical medicine and rehabilitation clinics. The first group will receive 10 sessions of pulsed electrical magnetic stimulation in the stenosis canal (25 Hz, 80 Gauss, 15 minutes per day) along with routine treatment (gabapentin 100, Williams exercise and anaheal,) and the second group will receive intensity 1 along with gabapentin 100, Williams exercise and anaheal. In order to blind the patients, the magnet will be set to 1 Gauss intensity in the control group so that patients will not know whether the device is on or off.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals over 50 years of age with a clinical diagnosis of lumbar canal stenosis based on the presence of back pain with intermittent neurological lameness confirmed by Lumbo Sacral MRI. Exclusion criteria: Back pain for less than 4 weeks, having undergone a physiotherapy program in the past 3 months

Intervention groups

The first group will receive pulsed electrical magnetic stimulation in the stenotic canal for 10 sessions (25 Hz, 80 Gauss, 15 minutes per day) along with routine treatment (Gabapentin 100, Williams exercise, and

Anaheal), and the second group will receive intensity 1 along with Gabapentin 100, Williams exercise, and Anaheal.

Main outcome variables

Reduce pain; reduce inflammation; increase patient function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180507039571N3**

Registration date: **2025-02-06, 1403/11/18**

Registration timing: **prospective**

Last update: **2025-02-06, 1403/11/18**

Update count: **0**

Registration date

2025-02-06, 1403/11/18

Registrant information

Name

Shervin Ghaffari hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-05, 1403/12/15
Expected recruitment end date
2025-07-06, 1404/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of pulsed electromagnetic field on pain intensity and function of patients with spinal stenosis compared to the control group referring to physical medicine clinics: A randomized controlled clinical trial study

Public title
Investigating the effect of pulsed electromagnetic field on pain intensity and function of patients with spinal stenosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals over 50 years of age with a clinical diagnosis of LCS based on the presence of low back pain with intermittent neurological lameness confirmed by LumboSacral MRI The ability to move independently Good mental and cognitive health Consent to participate in the study

Exclusion criteria:

Back pain for less than 4 weeks Clinical findings inconsistent with the diagnosis of LCS on MRI Having a physiotherapy program in the past 3 months Presence of progressive neurological deficit Infectious Spondylodiscitis such as Tuberculosis, Brucellosis, inflammatory Spondylitis Uncontrolled systemic diseases Liver or renal failure History of back surgery Presence of acute back trauma Lower limb surgery or unhealed fractures Pregnancy Epilepsy Implanted medical devices such as pacemakers, insulin pumps, or hepatic artery infusion pumps

Age
From **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of patients to the two intervention and control groups is done randomly by generating a random sequence of numbers by a computer. A researcher other than the principal investigator performs this process. Each patient is assigned a code in the order of their entry

into the study, and this code is placed in a sealed envelope and given to the principal investigator.

Blinding (investigator's opinion)
Single blinded

Blinding description
To blind patients, the magnet is set to an intensity of 1 Gauss in the control group so that patients are not aware that the device is on or off.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Isfahan University of Medical Sciences

Street address

Unit 1, No. 63, Arian Complex, 16th Meghdad Alley, Meghdad Avenue, Isfahan

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Province

Isfahan

Postal code

8184963602

Approval date

2025-01-12, 1403/10/23

Ethics committee reference number

IR.MUI.MED.REC.1403.426

Health conditions studied

1

Description of health condition studied

Lumbar Canal Stenosis

ICD-10 code

M48.06

ICD-10 code description

Spinal stenosis, lumbar region

Primary outcomes

1

Description

Back pain score on the Visual Analogue Scale questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and 14 days and 3 months after the end of treatment

Method of measurement

Using Visual Analogue Scale

2**Description**

Assessing patient performance using the Modified Oswestry questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and 14 days and 3 months after the end of treatment

Method of measurement

Using the Modified Oswestry Questionnaire

Secondary outcomes

empty

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

Intervention group: Pulse Electrical Magnetic Stimulation (Novinmed Company with a cylindrical solenoid applicator with a diameter of 70 cm) in the stenotic canal for 10 sessions (25 Hz, 80 Gauss, 15 minutes per day) along with routine treatment (Gabapentin 100 every night, Williams exercise one set of 10 twice a day and Anaheal every 12 hours)

Category

Treatment - Devices

2**Description**

Control group: Pulse Electrical Magnetic Stimulation (Novinmed Company with a cylindrical solenoid applicator with a diameter of 70 cm) in the stenotic canal for 10 sessions (25 Hz, 1 Gauss, 15 minutes per day) along with routine treatment (Gabapentin 100 every night, Williams exercise one set of 10 twice a day and Anaheal every 12 hours)

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amin hospital

Full name of responsible person

Shervin Ghaffari Hoseini

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Amin hospital, Sonbolestan Alley, Ibn Sina Avenue, Shohada Square, Isfahan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholam Reza Askari

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3rd floor, Vice President for Research and Technology of the University, 4th building, Isfahan University of Medical Sciences, Hezar Jarib Avenue, Isfahan

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Shervin Ghaffari Hoseini

Position

Researcher

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Isfahan Cardiovascular Research Institute, Shahid
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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Shervin Ghaffari Hoseini

Position

Researcher

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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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