Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
+98 31 3611 5208

Email address
shghaffari@yahoo.com

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

City

Isfahan

Province

Isfehan

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
Street address
Amin hospital, Sonbolestan Alley, Ibn Sina Avenue, Shohada Square, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3445 5051
Email
shghaffari@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholam Reza Askari
Street address
3rd floor, Vice President for Research and Technology of the University, 4th building, Isfahan University of Medical Sciences, Hezar Jarib Avenue, Isfahan
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3133
Email
intres@nui.ac.ir
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

Street address
Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, next to Shahid Chamran Heart Hospital, after Shahran Bridge, 3rd Mushtaq St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3611 5208

Email
shghaffari@yahoo.com

Person responsible for scientific 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

Street address
Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, next to Shahid Chamran Heart Hospital, after Shahran Bridge, 3rd Mushtaq St., Isfahan

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Province
Isfehan

Postal code
8174673461

Phone
+98 31 3611 5208

Email
shghaffari@yahoo.com

Person responsible for updating data

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

Street address
Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, next to Shahid Chamran Heart Hospital, after Shahran Bridge, 3rd Mushtaq St., Isfahan

City
Isfahan

Province
Isfehan

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8174673461

Phone
+98 31 3611 5208

Email
shghaffari@yahoo.com

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