Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Exploring the Role of Whole Body Electrical Muscle Stimulation in Weight Loss and Functional Enhancement for Individuals with Degenerative Joint Diseases of the Spine and Limited Physical Activity and High Body Mass Index

Protocol summary

Study aim
Determining the effect of electrical muscle stimulation on weight loss and improvement of functional disability in patients with degenerative spinal disease with high body mass index and limited physical activity

Design
Single-blinded Randomized Controlled Trial

Settings and conduct
This study will be conducted at Shahid Bahonar Hospital in Kerman as a single-blind, randomized controlled trial.

Participants/Inclusion and exclusion criteria
Inclusion criteria (summary): • Degenerative spinal condition diagnosed clinically and according to radiologic findings • Patients with limited mobility to perform activities according to the WIQ index (Score < 45) Exclusion criteria (summary): • Established neuromuscular disease. • History of spinal surgery in the past 6 months. • Severe or uncontrolled cardiovascular disease • Presence of metal implants in the body (except dental implants). • Presence of advanced degenerative knee disease

Intervention groups
Participants will be randomly assigned to one of three parallel groups: control group (CG), isometric exercise group (ISO) with isometric exercises and wearing WB-EMS clothing without electrical stimulation, and isometric exercise plus electromyostimulation (ISO + EMS) group with isometric exercises and wearing WB-EMS clothing with electrical stimulation.

Main outcome variables
-Anthropometric Measures - Walking Impairment Questionnaire (WIQ) - Low back pain intensity measured by the Numerical Rating Scale (NRS) - Health-related quality of life assessment using the Short Form-36 (SF-36) questionnaire - Functional capacity and exercise tolerance evaluated through the 6-Minute Walk Test (6MWT) - Cardiovascular endurance assessed via the Two-Stage Treadmill Test

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250513065709N1**
Registration date: **2025-08-03, 1404/05/12**
Registration timing: **prospective**

Last update: **2025-08-03, 1404/05/12**
Update count: **0**

Registration date
2025-08-03, 1404/05/12

Registrant information

Name
Reza Karimabadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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rkarimabadi09@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-06, 1404/05/15

Expected recruitment end date
2025-09-06, 1404/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Exploring the Role of Whole Body Electrical Muscle Stimulation in Weight Loss and Functional Enhancement for Individuals with Degenerative Joint Diseases of the Spine and Limited Physical Activity and High Body Mass Index

Public title

The effect of whole body electrical muscle stimulation on spinal diseases

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Degenerative spinal disease diagnosed clinically and according to radiologic findings Patients with limited mobility to perform activities according to the WIQ index (Score <45) Aged 50-79 years old Ability to understand and implement intervention instructions BMI equal to or greater than 30 kg/m2 Willingness to participate and signing an informed consent form

Exclusion criteria:

Established neuromuscular disease Established psychiatric disorders Diagnosed balance disorders and vertigo History of spinal surgery in the past 6 months Severe or uncontrolled cardiovascular disease, including uncontrolled blood pressure (systolic blood pressure > 180 mmHg or diastolic > 110 mmHg) or uncontrolled diabetes (HbA1c > 8%). Pregnancy or breastfeeding. Use of anticoagulants. Presence of metal implants in the body (except dental implants). Presence of red flags of back pain in patients. Presence of advanced degenerative knee disease Failure to continue training within eight weeks and willingness to withdraw from the study (Dropping) Active rheumatic diseases (such as rheumatoid arthritis, lupus, ankylosing spondylitis) that are not under control

Age

From **50 years** old to **79 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization process will be performed using random number generation software. In this regard, each eligible patient will be assigned a unique identification code to maintain confidentiality and facilitate unbiased randomization. Randomization will be performed using a random block design with variable size to ensure balance of group sizes throughout the study. Participants will be randomly assigned to one of the following three parallel groups: control group (CG), isometric exercise group (ISO) with isometric exercises and wearing a WB-EMS garment without electrical stimulation, and isometric exercise plus electromyostimulation (ISO + EMS) group with isometric exercises and wearing a WB-EMS garment with electrical stimulation.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study employs a single-blind design where outcome assessors and data collectors are blinded to group allocation, while participants acannot be blinded due to the nature of the intervention. Participants are aware of their group assignment as they can distinguish between receiving electrical stimulation (ISO + EMS group) versus wearing the WB-EMS suit without stimulation (ISO group) or no intervention (control group). However, outcome assessors who conduct anthropometric measurements, questionnaire administration, and functional tests (6MWT, Two-Stage Treadmill Test) are completely blinded to group allocation and will not have access to randomization records. Data collectors responsible for recording measurements and questionnaire responses are also blinded to treatment assignment. The statistical analyst will remain blinded to group allocation during data analysis until the final interpretation phase.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital-Kerman University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences, Kerman, Jahad Street, Somayeh Crossroads, Kerman

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Province

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Postal code

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Approval date

2025-05-11, 1404/02/21

Ethics committee reference number

IR.KMU.AH.REC.1404.030

Health conditions studied

1

Description of health condition studied
Neurodegenerative Spine Diseases
ICD-10 code
G32.0
ICD-10 code description
Subacute combined degeneration of spinal cord in diseases classified elsewhere

Primary outcomes

1

Description
Walking Impairment Questionnaire (WIQ) Score
Timepoint
Baseline and 8 weeks
Method of measurement
Standardized Walking Impairment Questionnaire (WIQ) questionnaire

2

Description
Low Back Pain Intensity
Timepoint
baseline and 8 weeks
Method of measurement
Numerical Rating Scale (NRS)

3

Description
Health-Related Quality of Life
Timepoint
baseline and 8 weeks
Method of measurement
Short Form-36 questionnaire (SF-36)

4

Description
6-Minute Walk Test Distance
Timepoint
baseline and 8 weeks
Method of measurement
Measured as total distance walked in meters over 6 minutes on flat 30-meter course.

5

Description
Two-Stage Treadmill Test Duration
Timepoint
baseline and 8 weeks
Method of measurement
Measured as walking time in seconds during second stage at 3 km/h with 10% incline.

6

Description
Anthropometric Measures
Timepoint
baseline and 8 weeks
Method of measurement
BMI, waist Circumference, and hip Circumference will be measured by standardized meter and scale.

7

Description
Body Composition
Timepoint
baseline and 8 weeks
Method of measurement
segmental direct multi-frequency bioelectrical impedance analysis.

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Participants only receive standard care including education on ergonomic principles and spinal care, light stretching and strengthening exercise program appropriate to patient condition, nutritional counseling for weight management, and regular follow-up by the treatment team without any electrical muscle stimulation intervention.
Category
N/A

2

Description
Intervention group 1: Isometric Exercise Group (ISO): Participants wear WB-EMS suits without electrical stimulation and perform supervised isometric exercises twice weekly on non-consecutive days for 30 minutes per session over 8 weeks, including 20 minutes of main training with 6-second contraction and 4-second rest intervals, plus 5-minute warm-up and cool-down periods with stretching movements.
Category
Rehabilitation

3

Description
Intervention group 2: Isometric Exercise + Electromyostimulation Group (ISO + EMS): Participants wear WB-EMS suits with electrical stimulation and perform the same supervised isometric exercise protocol as the ISO group, with electrical stimulation intensity progressing from 60% of maximum tolerable stimulation (MT1) during weeks 1-4, to 70% MT1 during weeks 5-6,

and 80% MT1 during weeks 7-8, using 85 Hz frequency and 350 microsecond pulse width.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kerman Shahid Bahonar Hospital

Full name of responsible person

Reza Karimabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hamid Sharifi

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Reza Karimabadi

Position

Assistant

Latest degree

Medical doctor

Other areas of specialty/work

Neurosurgery

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Position

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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
No - There is not 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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available