

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Construction and evaluation of the effect of Thoracolumbosacral Orthosis with Transcutaneous Electrical Nerve Stimulation Mechanism on balance, walking speed, and pain in Individuals with chronic Spinal Cord Injury

Protocol summary

Study aim

The aim of this study is to achieve simultaneous trunk stabilization and transcutaneous electrical stimulation at the lumbosacral level using a Thoracolumbosacral Orthosis (TLSO) equipped with a functional electrical stimulation mechanism, in order to investigate and evaluate its effect on improving balance, increasing walking speed, and reducing pain in individuals with chronic spinal cord injury.

Design

A quasi-experimental, within-subject design trial comparing the effects of the TLSO with TENS mechanism versus the TLSO only, with randomized sequence of exposure to the conditions.

Settings and conduct

This trial will be conducted at the research centers of the University of social welfare and rehabilitation sciences, recruiting volunteers through public announcements. Participants will be evaluated in two randomized phases: first with the TLSO brace and electrical stimulation (TENS), and subsequently with the TLSO brace only. Due to the nature of the intervention, blinding the participants is not feasible.

Participants/Inclusion and exclusion criteria

Individuals with non-progressive/chronic spinal cord injury (SCI) at the C4-C9 level.- At least 12 months passed since the time of injury.- Ability to walk or use a walking assistive device. -Exclusion Criteria:- Maximum age of 18 years .- Women with positive pregnancy tests or who must not become pregnant (if of child-bearing age).- Presence of neuropathic pain with a score of more than 4 on the neuropathic pain scale.

Intervention groups

Participants will receive treatment in a randomized sequence using two conditions: Designed Thoracolumbosacral Orthosis (TLSO) equipped with a Transcutaneous Electrical Nerve Stimulation (TENS)

mechanism. Thoracolumbosacral Orthosis (TLSO) without the TENS mechanism.

Main outcome variables

The main outcome variables are Balance, Walking Speed, and Pain in individuals with chronic spinal cord injury.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240514061793N3**

Registration date: **2025-10-03, 1404/07/11**

Registration timing: **prospective**

Last update: **2025-10-03, 1404/07/11**

Update count: **0**

Registration date

2025-10-03, 1404/07/11

Registrant information

Name

Hanieh Khaliliyan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-10-04, 1404/07/12

Expected recruitment end date

2026-10-04, 1405/07/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Construction and evaluation of the effect of Thoracolumbosacral Orthosis with Transcutaneous Electrical Nerve Stimulation Mechanism on balance, walking speed, and pain in Individuals with chronic Spinal Cord Injury

Public title

Using Electrical Stimulation to Improve Balance and Daily Activities in Spinal Cord Injury Patients

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients diagnosed with spinal cord injury confirmed by clinical and imaging findings. Age between 40 and 70 years. Ability to walk at least 10 meters with or without assistive devices. Stable medical condition for at least one month prior to enrollment. No severe cognitive impairment (MMSE score ≥ 24). Willingness to participate and provide informed consent.

Exclusion criteria:**Age**

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **8**

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of interventions will be randomized. Randomization will be performed using a block randomization method. The random sequence will be generated using a computer software (Random Allocation Software, version 2.0). Allocation concealment will be ensured by using sealed, opaque, and sequentially numbered envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Boulevard, Qods Boulevard, Central Headquarters of Tehran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۱۷۹۳۵۸۴

Approval date

2025-09-21, 1404/06/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1404.377

Health conditions studied**1****Description of health condition studied**

Lumbar level spinal cord injury

ICD-10 code

S34.1

ICD-10 code description

Other and unspecified injury of lumbar and sacral spinal cord

Primary outcomes**1****Description**

Balance score of timed up and go test

Timepoint

Immediately post intervention

Method of measurement

Timed up and go test

2**Description**

Speed score of six meter walk test

Timepoint

Immediately post intervention

Method of measurement

Six meter walk test

3**Description**

Pain intensity measured on the Visual Analog Scale for pain

Timepoint

Immediately post intervention

Method of measurement

Visual Analog Scale

Secondary outcomes

empty

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

Intervention group: Participants in this group will use a thoracolumbosacral orthosis with neuro-mechanical features. After receiving training on proper usage and completing baseline tests without the orthosis, participants will wear the orthosis and repeat the tests while using it.

Category

Rehabilitation

2**Description**

Intervention group: Participants in the same group will use a conventional thoracolumbosacral orthosis. After receiving training on proper usage and completing baseline tests without the orthosis, participants will wear the orthosis and repeat the tests while using it.

Category

Rehabilitation

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

Technical orthopedic clinic of rehabilitation school, University of Social Welfare and Rehabilitatio

Full name of responsible person

Reza Vahab Kashani

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Kodakyar Ave., Daneshjo Blvd., Evin, Velenjak

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

Tehran University of Medical Sciences

Full name of responsible person

Ramin Kordi

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Keshavarz Boulevard, corner of Qods Street, Central Organization Building of the University, 6th Floor, Research and Technology Vice-Chancellery

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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

Tehran 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**

University of social welfare and rehabilitation sciences

Full name of responsible person

Mahmood Bahramizadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study data will be shared with other researchers.

When the data will become available and for how long

Information is shared after the results are printed or summarized.

To whom data/document is available

Researchers working in academic institutions.

Under which criteria data/document could be used

By performing statistical tests on the data, the applicants can evaluate the results of using the interventions of this study on balance, walking speed, and pain and use these data to conduct meta-analysis review studies.

From where data/document is obtainable

Individuals can request information from the person in charge.

What processes are involved for a request to access data/document

Requests should be sent to Dr. Mahmood Bahramizadeh (ma.bahramizadeh@uswr.ac.ir).

Comments