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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+98 31 3792 5014

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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
۱۴۱۷۹۳۵۸۴۰
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
Street address
Kodakyar Ave., Daneshjo Blvd., Evin, Velenjak
City
Tehran
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1985713871
Phone
+98 21 7173 2000
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mbzoandp@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramin Kordi
Street address
Keshavarz Boulevard, corner of Qods Street, Central Organization Building of the University, 6th Floor, Research and Technology Vice-Chancellery
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Postal code
141765383761
Phone
+98 21 8163 3698
Email
vcr@tums.ac.ir
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

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

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Position
Professor

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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