Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the immediate effect of the novel spring-damper ankle-foot orthosis on margin of stability of affected and unaffected limbs during walking of patients diseased to multiple sclerosis with drop foot

Protocol summary

Study aim

Study of the immediate effect of a new spring-damper ankle-foot orthosis on the stability range of the healthy and affected limbs during walking in patients with multiple sclerosis and unilateral foot drop

Design

A single-group clinical trial (without control group) designed as a before-and-after comparison of affected and non-affected sides with itself, on 12 patients where blinding is not possible, but the order of data collection for the orthosis-wearing and shoe-only conditions will be randomized.

Settings and conduct

Patients with unilateral foot drop due to multiple sclerosis and residing in Tehran will participate in this study. The research will be conducted to determine the immediate effect of using the intervention (new articulated orthosis) on the affected side on the parameters of both the healthy and affected sides, and for this purpose, gait data with the orthosis and without the orthosis will be compared. The nature of the use of the orthosis and data collection makes it impossible to blind the data collection for any of the volunteers and the researcher. Data collection will be conducted in Tehran.

Participants/Inclusion and exclusion criteria

Diagnosed with multiple sclerosis; unilateral foot drop; has the ability to walk independently without a cane

Intervention groups

A self-controlled study examines the immediate effects of a spring-damper orthosis on both legs in multiple sclerosis patients with unilateral foot drop, without a control group

Main outcome variables

Age; Gender; Height; Weight; Berg Balance Scale score; Heel contact stability range in anterior-posterior direction; Heel contact stability range in medial-lateral direction; Mid-stance stability range in anterior-posterior direction; Mid-stance stability range in medial-lateral direction; Step length; Step width; Expanded Disability Status Scale (EDSS) score; Spasticity level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058315N3**
Registration date: **2025-08-12, 1404/05/21**
Registration timing: **prospective**

Last update: **2025-08-12, 1404/05/21**
Update count: **0**

Registration date

2025-08-12, 1404/05/21

Registrant information

Name

Nahid Tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the immediate effect of the novel spring-damper ankle-foot orthosis on margin of stability of affected and unaffected limbs during walking of patients diseased to multiple sclerosis with drop foot

Public title

The immediate effect of the novel spring-damper ankle-foot orthosis on margin of stability of affected and unaffected limbs during walking of patients diseased to MS

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adults with unilateral foot drop caused by multiple sclerosis Ability to walk at least 25 steps without assistance Ability to complete at least 25 steps within a duration of 8 to 45 seconds Maximum grade of 3- (minus) in the manual muscle strength test for dorsiflexors and grade 3+ (plus) in knee extensor muscles Ability to walk without orthoses for up to ten meters Ability to achieve at least 5 degrees of passive dorsiflexion Completion of the Four Square Step Test (FSST) in less than 15 seconds

Exclusion criteria:

Having cardiovascular or respiratory problems Presence of limb impairment or amputation on the opposite side Concurrent use of other treatment methods (e.g., physiotherapy or surgery) during the study Having perceptual-cognitive impairments Presence of polyneuropathy Instability and imbalance while standing or walking Severe visual or hearing impairment History of spinal fracture or pain Participant's unwillingness to continue cooperation Absence of spasticity greater than grade 3 in the plantar flexor muscles (according to the Ashworth scale) scoring less than 5 on the disability scale

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh

City

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Province

Hamadan

Postal code

6517838840

Approval date

2025-07-26, 1404/05/04

Ethics committee reference number

IR.UMSHA.REC.1404.315

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Margin of stability

Timepoint

After 5 minutes adaptation with orthosis

Method of measurement

Viacon motion analysis system and Kistler force plate

Secondary outcomes

1

Description

Stride length

Timepoint

Immediately after receiving the orthosis

Method of measurement

Viacon Motion Analysis System

2

Description
Stride width
Timepoint
Immediately after receiving the orthosis
Method of measurement
Viacon Motion Analysis System

Intervention groups

1

Description
Intervention group: Each participant will be evaluated under two conditions: wearing shoes on both sides, and wearing a shoe on the unaffected side along with the new spring-damper orthosis on the affected side, with the evaluation order randomized and a 5-minute rest period between conditions. Kinematic assessment will involve evaluating center of mass (COM) displacement velocity by tracking a sacral marker using a Vicon motion analysis system equipped with six infrared cameras recording at 120 Hz, while two Kistler force plates sampling at 1200 Hz will be used to assess plantar center of pressure (COP) and COM, with synchronized data collection from both the motion capture system and force plates, all conducted at the Mofaghian Research Center in Tehran. There is no control group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Occupational Therapy Clinic, Faculty of Rehabilitation Sciences, University of Iran, Tehran
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Vice President for Research and Technology, Hamadan University of Medical Sciences
Grant code / Reference number
۴۶۵۲۴
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not 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