Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the impact of leading limb and six weeks of using new spring-damper and posterior Leaf Spring ankle-foot orthoses on the gait initiation event in hemiplegic patients with dropped foot due to stroke

Protocol summary

Study aim

Comparison of the effect of leading limb and six weeks of using the novel spring-damper and posterior leaf spring ankle orthoses on gait initiation in hemiplegic patients with drop foot due to stroke

Design

parallel randomized controlled trial

Settings and conduct

Data will be collected at Dr. Javad Mofavaghian Biomechanical Research Center in Tehran. To blind the effect of the experimenter's knowledge on the evaluation of the results, participants will be asked to hide their orthosis under their clothes and inside their shoes at all times while in the laboratory and performing the tests. The data analyst will not be aware of the differences between the intervention groups.

Participants/Inclusion and exclusion criteria

Age over 65 years, at least 6 months after stroke, ability to walk outdoors, foot drop due to central and peripheral nerve-related, maximum strength of three negatives on the manual muscle strength assessment test in the dorsiflexor muscles, individuals with spasticity less than two, based on the modified Ashworth criteria for patients with central nerve injury, ability to walk for more than thirty minutes with orthosis

Intervention groups

The novel Hybrid passive spring-damper ankle foot orthosis Posterior leaf spring

Main outcome variables

The displacement of the center of pressure in each of the anterior-posterior(AP) and medial-lateral (ML) planes, the gait initiation' velocity, the amount of ground reaction force (GRF) in each of the AP and ML planes, the GRF's impulse

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058315N2**
Registration date: **2025-01-25, 1403/11/06**
Registration timing: **prospective**

Last update: **2025-01-25, 1403/11/06**
Update count: **0**

Registration date

2025-01-25, 1403/11/06

Registrant information

Name

Nahid Tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1633

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2026-01-21, 1404/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the impact of leading limb and six weeks of using new spring-damper and posterior Leaf Spring ankle-foot orthoses on the gait initiation event in hemiplegic patients with dropped foot due to stroke

Public title
The effect of an orthosis on gait initiation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 65 years at least 6 months after stroke ability to walk outdoors foot drop due to central and peripheral nerve-related maximum strength of three negatives on the manual muscle strength assessment test in the dorsiflexor muscles individuals with spasticity less than two, based on the modified Ashworth criteria for patients with central nerve injury ability to walk for more than thirty minutes with orthosis
Exclusion criteria:
Any history of using foot-foot orthoses inability to see obstacles or instructions during the test severe cardiac/respiratory problems severe bone deformities presence of acute orthopedic or neurological diseases that affect balance presence of acute vision and hearing problems presence of pathologies that increase the risk of falling (Parkinson's).
Age
From **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **16**
At the beginning of the study, participants will be randomly assigned to the posterior leaf spring orthosis and the novel spring-damper orthosis according to the Treatment adaptive randomization method. After the first data collection, the volunteer will return to the laboratory after at least six weeks of orthosis use, and the tests will be repeated and the data will be collected again. At each data collection session, each volunteer's gait initiation will be assessed in four conditions in terms of leading limb selection (affected/un-affected side) and gait initiation with shoes/wearing the orthosis (posterior leaf spring and new spring-damper orthosis depending on the intervention group). Successful data collection will be repeated three times, and the volunteer will be given a 2-minute rest period between each test to prevent patient fatigue.
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
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
Hamadan
Province
Hamadan
Postal code
6517838840
Approval date
2025-01-18, 1403/10/29
Ethics committee reference number
IR.UMSHA.REC.1403.756

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
164
ICD-10 code description
Other specified cerebrovascular diseases

Primary outcomes

1

Description
The effect of wearing an orthosis on the displacement of the center of pressure in the anterior-posterior direction
Timepoint
Data will be measured once after the volunteer enters the study and once after at least six weeks of using the intervention.
Method of measurement
Using the Kistler force platform

2

Description
The effect of wearing an orthosis and leading limb on the displacement of the center of pressure in the medial-lateral direction

Timepoint
Data will be measured once after the volunteer enters the study and once after at least six weeks of using the intervention.
Method of measurement
Using the Kistler force platform

Secondary outcomes

1

Description
The effect of wearing orthosis on the value of the ground reaction force in the anterior-posterior direction
Timepoint
At the study onset and after at least six weeks of using the orthosis
Method of measurement
using the Kistler's force platform

2

Description
The effect of using an orthosis on the amount of ground reaction force in the medial-lateral direction
Timepoint
At the study onset and after at least six weeks of using the orthosis
Method of measurement
using the Kistler's force platform

3

Description
The effect of using an orthosis on the magnitude of the ground reaction force impulse
Timepoint
At the study onset and after at least six weeks of using the orthosis
Method of measurement
using the Kistler's force platform

4

Description
The effect of using an orthosis on the velocity of gait initiation
Timepoint
At the study onset and after at least six weeks of using the orthosis
Method of measurement
Dividing the distance traveled by the body's center of pressure by the time elapsed at the gait initiation

5

Description
Duration of gait initiation
Timepoint
At the study onset and after at least six weeks of using the orthosis
Method of measurement
using the Kistler's force platform

Intervention groups

1

Description
Intervention group: using the posterior leaf spring
Category
Rehabilitation

2

Description
Intervention group: Using the Novel Hybrid Passive spring-damper ankle foot orthosis
Category
Rehabilitation

Recruitment centers

1

Recruitment center
City
Tehran
Province
Tehran

2

Recruitment center
Name of recruitment center
Physiotherapy Clinic, Faculty of Rehabilitation
Full name of responsible person
Ensieh Pourhoseingholi
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Mirdamad
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Email
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Web page address
https://rehab.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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Province
Hamadan
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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
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
Hamedan University of Medical Sciences
Full name of responsible person
Nahid Tafti
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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
No further information available.

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