Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Immediate and after 6 weeks effect of newly design articulated Ankle Foot Orthosis on postural control in static and dynamic conditions in drop foot post stroke

Protocol summary

Study aim

Comparison of the effect of newly designed articulated ankle-foot orthosis and posterior leaf spring on postural control and COP in static and dynamic conditions in stroke patients.

Design

A single-blind, quasi-experimental, parallel group trial with repeated measures on 20 stroke patients

Settings and conduct

This is a single-blind quasi-experimental study with repeated measures on 20 hemiplegic stroke patients (with drop foot). Simple non-probability sampling will be performed from patients referred to orthotics clinics in Tehran. Eligible participants will be randomly assigned to two parallel groups (newly designed articulated AFO and posterior leaf spring AFO). Location: Biomechanics Research Center of Sharif University of Technology (Kistler force plate). Procedure: Assessments will be conducted in two stages (immediately after receiving the orthosis and after 6 weeks of continuous use) under four conditions (hard/foam surface with eyes open/closed). The outcome assessor and statistical analyst will be blinded.

Participants/Inclusion and exclusion criteria

inclusion criteria : age 40 and 65 years, dorsiflexion weakness, spasticity max grade 1, at least 6 months post-stroke, ability to walk independently, and daily use of PLS. Exclusion criteria: history of cardiovascular and pulmonary diseases, joint contracture, knee hyperflexion, hammer toes, severe visual impairment, and poor balance.

Intervention groups

Participants will be assigned to two equal parallel groups: Group 1: Using a standard ankle-foot orthosis (posterior leaf spring) for 6 weeks. Group 2: Using a newly designed articulated ankle-foot orthosis for 6 weeks. Data from the condition before using the orthosis (wearing shoes only) will be considered as the control condition.

Main outcome variables

1. COP sway in AP and ML directions 2. Mean COP velocity 3. Path length 4. Ellipse area

General information

Reason for update

Acronym

NAFO (newly designed articulated ankle foot orthosis)

IRCT registration information

IRCT registration number: **IRCT20201110049330N1**
Registration date: **2026-10-09, 1405/07/17**
Registration timing: **prospective**

Last update: **2026-10-09, 1405/07/17**
Update count: **0**

Registration date

2026-10-09, 1405/07/17

Registrant information

Name

Zahra Soltani hanafi por

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3821 5062

Email address

nesa.soltani.hp@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-24, 1405/08/02

Expected recruitment end date

2026-12-23, 1405/10/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Immediate and after 6 weeks effect of newly design articulated Ankle Foot Orthosis on postural control in static and dynamic conditions in drop foot post stroke

Public title

Effect of immediate and short-term use of two new Ankle-Foot- Orthosis on balance in stroke pations

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40 and65 years weakness of ankle dorsiflexor muscles at least 6 month since stroke onset no involvement or problem in contralateral limb ability to walk independent without an assistive device daily use of Posterior Leaf Spring (pls) orthosis absence of knee hyperflexion No use of a cane on the unaffected side during walking (since a cane on the unaffected side affects the affected side) Modified Ashworth Scale score of less than 2 Ability to follow and respond to instructions given by the examiner Spasticity of plantar flexor muscles with a maximum grade of 2 based on the Modified Ashworth Scale

Exclusion criteria:

History of cardiovascular and pulmonary disease Fixed contracture in the ankle, hip, and knee joints Patients with knee hyperflexion Presence of hammer toes5. Patients with severe visual impairment6. Individuals with very poor balance based on the Timed Up and Go (TUG) test

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, participants will be randomly assigned to two equal groups using a simple lottery method. One group will receive the standard intervention (posterior leaf spring AFO) and the other group will receive the newly designed articulated AFO for a period of 6 weeks.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study utilizes a single-blind design. Due to the visual and physical nature of the ankle-foot orthoses and the type of intervention, blinding of the participants and the healthcare providers (the orthotist fitting the device) is not possible. However, the outcome assessor (the individual recording and extracting force plate data) will be blinded to the group allocation and the type of intervention. Additionally, the data collectors and the statistical analyst will be blinded to the group codes to minimize bias. Data will also be monitored by a Data Safety and Monitoring Committee."

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Central Headquarters of Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Research Sq., Hamadan

City

Hamedan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2026-09-14, 1405/06/23

Ethics committee reference number

IR.UMSHA.REC.1405.484

Health conditions studied

1

Description of health condition studied

stroke (hemiplegia) with drop foot

ICD-10 code

G81.90

ICD-10 code description

Hemiplegia, unspecified affecting unspecified side

Primary outcomes

1

Description

Center of Pressure (COP) sway in anterior-posterior (AP) and medial-lateral (ML) directions, mean COP velocity, path length, and ellipse area. These parameters will be

measured using a Kistler force plate (Model 9260AA) at 100 Hz at the Biomechanics Research Center of Sharif University of Technology.

Timepoint

Measurements will be performed at two time points:1. Immediately after receiving the orthosis (baseline)2. After 6 weeks of continuous use of the orthosis (follow-up)

Method of measurement

Center of Pressure (COP) parameters will be measured using a Kistler force plate (Model 9260AA) at a sampling frequency of 100 Hz at the Biomechanics Research Center of Sharif University of Technology. Raw data will be analyzed in MATLAB software after filtering with a Butterworth filter (cutoff frequency 10 Hz).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group (Group 1): Using a standard ankle-foot orthosis (posterior leaf spring) for 6 weeks. new intervention (Group 2): Using a newly designed articulated ankle-foot orthosis for 6 weeks. Data from the condition before using the orthosis (wearing shoes only) will be considered as the control condition.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

;Orthotics and Prosthetics Clinics in Tehran (in collaboration with the Biomechanics Research Center

Full name of responsible person

Ensieh pourhossiengholi

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school of Rehabilitation Sciences, Hamedan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Alireza Soltanian

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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

80

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

Zahra Soltani Hanafi Por

Position

instructor

Latest degree

Master

Other areas of specialty/work

Others

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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
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Full study protocol, informed consent form, and raw data related to Center of Pressure (COP) parameters, which will be anonymized.
When the data will become available and for how long
Access to the protocol and informed consent form will be available upon registration in the IRCT. Access to raw data and final results will be provided 6 months after the study completion and article publication
To whom data/document is available
Academic researchers and scientific-research institutions who submit a written request and obtain approval from the Ethics Committee for scientific use of the data.
Under which criteria data/document could be used
Solely for research and scientific purposes, with proper citation, and without any commercial use. Data usage is contingent upon maintaining the confidentiality of participants' information.
From where data/document is obtainable
Requestors can contact the principal investigator, Ms. Zahra Soltani Hanafipour, via email (nesa.soltani.hp@gmail.com) to obtain the data or documents. They may also refer to the address of the Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences.
What processes are involved for a request to access data/document
The request process includes the following steps: 1. Sending a written request to the principal investigator via email. 2. Review of the request by the research team and approval by the Ethics Committee. 3. Signing a Confidentiality Agreement by the requestor. 4. Sending anonymized data via secure email. This process typically takes a maximum of one month.
Comments