Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the immediate effect and overall efficacy of a new hybrid passive spring-damper ankle-foot orthosis compared to a traditional solid ankle-foot orthosis on the dynamic stability of both involved and non-involved sides in hemiplegic individuals with foot drop due to cerebral palsy after 6 weeks of use

Protocol summary

Study aim

Investigating the immediate effect and overall efficacy of a new hybrid passive spring-damper ankle-foot orthosis compared to a traditional solid ankle-foot orthosis on the dynamic stability of both involved and non-involved sides in hemiplegic individuals with foot drop due to cerebral palsy after 6 weeks of use

Design

Phase III randomized, parallel group, double-blind trial with a sample size of 24 people

Settings and conduct

In the Biomechanics Laboratory of the Javad Mofavaghian Neurological Rehabilitation Center, patients were non-randomly divided into two groups of 12, each receiving a type of orthosis: a solid ankle orthosis and a damper spring. Kinetic and kinematic data were measured using a Kistler force plate and 6 Vicon infrared cameras, and parameters related to dynamic stability were obtained from these data using mathematical calculations in Matlab software.

Participants/Inclusion and exclusion criteria

Participants were adults aged 18 to 55 years who used a Solid ankle-foot orthosis daily. They had to be free of significant disabling limitations or contractures in the contralateral or ipsilateral joints, able to walk independently with or without the use of an ankle orthosis, have a functional assessment score of 1 to 2, and be able to perform at least 5 degrees of active or passive dorsiflexion.

Intervention groups

Using two types of ankle foot orthoses: solid and spring damper

Main outcome variables

Postural stability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190919044818N6**
Registration date: **2025-09-07, 1404/06/16**
Registration timing: **prospective**

Last update: **2025-09-07, 1404/06/16**
Update count: **0**

Registration date

2025-09-07, 1404/06/16

Registrant information

Name

Ensieh Pourhosaingholi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4480 3255

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

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

Investigating the immediate effect and overall efficacy of a new hybrid passive spring-damper ankle-foot orthosis compared to a traditional solid ankle-foot orthosis on the dynamic stability of both involved and non-involved sides in hemiplegic individuals with foot drop due to cerebral palsy after 6 weeks of use

Public title

Investigation of the immediate effect and overall efficacy of a new passive hybrid spring-damper ankle-foot orthosis for dynamic stability

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults between 18 and 55 years old Daily use of Solid ankle-foot orthosis Ability to walk independently with or without the use of an ankle foot orthosis Gross motor function measurement scale between 1 and 2 Ashworth scale between 1 and 3 Ability to perform at least 5 degrees of active or passive dorsiflexion

Exclusion criteria:

The presence of cognitive problems that prevent understanding the researcher's instructions. Botulism toxin injection in the last 9 months Having vision or hearing problems Marked disabling limitation or contracture in the joints of the opposite limb or higher joints on the same side

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were assigned to groups using both sequential and block randomization methods, based on a computer-generated random number list. An independent researcher utilized statistical software to randomly allocate subjects into experimental and control groups. The allocation was done in a 1:1 ratio using random blocks of size two. The allocation sequence was kept hidden from the researcher responsible for registration and evaluation, and participants were numbered in order.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, outcome assessors, and data analysts are unaware of the study group assignments.

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

Hamadan, Shahid Fahmideh Blvd., Hamadan University of Medical Sciences, Faculty of Rehabilitation, Orthotics and Prosthetics Department

City

همدان

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2025-07-26, 1404/05/04

Ethics committee reference number

IR.UMSHA.REC.1404.270

Health conditions studied

1

Description of health condition studied

Cerebral palsy

ICD-10 code

G80

ICD-10 code description

Cerebral palsy

Primary outcomes

1

Description

Dynamic stability

Timepoint

Before intervention, immediately after the study, 6 weeks after intervention

Method of measurement

Using a Force plate and 6 ultraviolet camera

Secondary outcomes

1

Description
Postural stability
Timepoint
4 month
Method of measurement
Vicon infrared camera, Kistler force plate

Intervention groups

1

Description
Intervention group: The treatment protocol involved utilizing a researcher-solid ankle foot orthosis model. During the intervention, detailed kinetic and kinematic gait analyses were conducted using the Vicon MX-40 infrared camera system (UK-made) alongside the Kistler 9286AA force plate (manufactured in the USA) to precisely capture patient movement patterns. Each patient underwent a one-hour testing session, split into two appointments spaced six weeks apart. At the start of each session, patients were given a 10-minute orientation to familiarize themselves with the laboratory setting and to receive instructions on the testing procedures.
Category
Rehabilitation

2

Description
Intervention group: The treatment protocol involved utilizing a researcher-developed spring damper ankle foot orthosis model. During the intervention, detailed kinetic and kinematic gait analyses were conducted using the Vicon MX-40 infrared camera system (UK-made) alongside the Kistler 9286AA force plate (manufactured in the USA) to precisely capture patient movement patterns. Each patient underwent a one-hour testing session, split into two appointments spaced six weeks apart. At the start of each session, patients were given a 10-minute orientation to familiarize themselves with the laboratory setting and to receive instructions on the testing procedures.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Occupational Therapy Clinic, Iran University of Medical Sciences
Full name of responsible person
Ensieh Pourhoseingholi
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Orthotics and Prosthetics Department, Faculty of Rehabilitation, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd., Hamedan, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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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
Ensieh Pourhoseingholi
Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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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

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Parameters related to dynamic stability include the speed and direction of movement of the center of pressure and the center of mass of the body.

When the data will become available and for how long

Immediately after sampling in 1404

To whom data/document is available

Researchers

Under which criteria data/document could be used

Conducting more research in the field of health

From where data/document is obtainable

Ensieh Pourhoseingholi, Faculty of Rehabilitation, Hamadan University of Medical Sciences

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

Immediately after the article is published and via email

Comments