

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Efficacy of Posterior Leaf Spring Ankle Foot Orthosis on biomechanical parameters of drop foot post stroke patients

Protocol summary

Study aim

The aim of this study is to determine the effect of Posterior Leaf Spring AFO on biomechanics of drop foot in stroke population.

Design

This clinical trial will conduct in only one group in Movafaghian gait analysis center on 20 drop foot post stroke drop foot population.

Settings and conduct

At the beginning of the examination, the patients were asked to walk at least for 10 to 20 min with their own PLS AFOs/shoes. After that, retro-reflective markers were set at anatomical landmarks according to Helen Hayes's method. Then, each one will walk in front of Vicon cameras and on the Kistler force plate to capture biomechanical parameters. Data processing will process by Vicon software.

Participants/Inclusion and exclusion criteria

The inclusion criteria were a clinically observed unilateral drop-foot using PLS AFO as a routine AFO and ability to walk at least 20 min without assistance

Intervention groups

Obtaining kinetic and kinematic of walking in gait laboratory with the use of Posterior Leaf Spring AFO in one session of 60 minute with and without posterior leaf spring AFO

Main outcome variables

Kinetic parameters of walking included the ankle, knee and hip moments and powers Kinetic parameters of walking included the ankle, knee and hip angles

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190919044818N3**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Ensieh Pourhosaingholi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4480 3255

Email address

ensiehpmd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Posterior Leaf Spring Ankle Foot Orthosis on biomechanical parameters of drop foot post stroke patients

Public title

Efficacy of Ankle Foot Orthosis on stroke

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

unilateral drop-foot using PLS AFO as a routine AFO
ability to walk at least 20 min without assistance
Exclusion criteria:
severe heart or metabolic disease previous abnormalities
in visual/vestibular functions emotional instability
previous fracture of both lower limbs severe poly
neuropathy presence of muscle spasms or contractures
in lower extremity joints

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **20**

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

Ethical committee of Hamadan university of medical
science

Street address

Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences Shahid Fahmideh Aven., Hamadan,
Iran

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۷۳۶

Approval date

2023-07-05, 1402/04/14

Ethics committee reference number

IR.UMSHA.REC.1402.280

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The angle of the ankle, knee and hip

Timepoint

Before intervention and immediately after intervention

Method of measurement

By using camera

2

Description

Moment of the ankle, knee and hip

Timepoint

Before intervention and immediately after intervention

Method of measurement

By using camera and force plate

3

Description

power of the ankle, knee and hip

Timepoint

Before intervention and immediately after intervention

Method of measurement

By using camera and force plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Obtaining kinetic and kinematic of
walking in gait laboratory with the use of Posterior Leaf
Spring AFO in one session of 60 minute with and without
posterior leaf spring AFO

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Gait analysis center of Movafaghian

Full name of responsible person

Ensieh Pourhoseingholi

Street address

Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of
Medical Sciences Shahid Fahmideh Aven..., Hamadan,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokohi

Street address

Department of Orthotics and Prosthetics, School of
Rehabilitation Sciences, Hamadan University of
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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 Proffessor

Latest degree

Ph.D.

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Biomechanical parameters of walking in drop foot foot post stroke

When the data will become available and for how long

Start of accessperiod from 1403

To whom data/document is available

Researchers

Under which criteria data/document could be used

Performing research in health service system

From where data/document is obtainable

Ensieh Pourhoseingholi, Hamadan university of medical science, orthosis and prosthesis department

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

After publication of arthicle from e-mail

Comments