Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 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 theeEffect 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 analyzis 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 fKistler orce plate to capture biomechanical parameters. Data processing will proces by Vicon sof ware.

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 libratory 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 commitee 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 immidiatly after intervention
Method of measurement
By using camera

2

Description
Moment of the ankle, knee and hip
Timepoint
Before intervention and immidiatly after intervention
Method of measurement
By using camera and force plate

3

Description
power of the ankle, knee and hip
Timepoint
Before intervention and immidiatly 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 libratory 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, Iran

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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 Medical Sciences Shahid Fahmideh Aven.., Hamadan, Iran

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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
Assisstant Proffessor

Latest degree
Ph.D.

Other areas of specialty/work
Others

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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 acsessperiod 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