Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Investigating the efficacy of new arthiculated AFO on biomechanical parameters in gait of multiple sclerosis

Protocol summary

Study aim
Comparison the biomechanical gait efficacy (kinetic, kinematic and spatiotemporal) newly designed Ankle Foot Orthosis on Multiple sclerosos

Design
Clinical trial, without blinding, phase 2 with 12 patients

Settings and conduct
At the start of examination, fifteen retro reflexive markers were attached based on modified Helen Hyes marker markers placed bilaterally on the anterior and posterior superior iliac spine, the posterior sacrum, medial and lateral femoral condyles. heel, lateral malleolus, top of the second metatarsal phalangeal joint (toe). Then, all stage of the examination was explained to the participants and wants them to walk with self selected walking speed in 10 meters at walkway in two conditions of with shoes only /with the new orthosis and shoes. The patients had 10 min of rest between each trial. Each trial was repeated five times.

Participants/Inclusion and exclusion criteria
Subjects diagnosed with MS (6 months), the extended disability scale EDSS of 4 to 6, unilateral drop foot, endurance to ambulate at least 30 feet continuously with minimal assist or less without the use of an AFO, the maximum spasticity of grade II (Ashworth scale) with plantar flexor muscles, and history of using passive AFO were entered in this study.

Intervention groups
Newly designed Ankle Foot Orthosis

Main outcome variables
Spatiotemporal parameters, Kinematic parametrs, kinetic parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190919044818N2**
Registration date: **2023-03-19, 1401/12/28**
Registration timing: **prospective**

Last update: **2023-03-19, 1401/12/28**
Update count: **0**

Registration date
2023-03-19, 1401/12/28

Registrant information

Name
Ensieh Pourhosaingholi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4480 3255

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ensiehpmd@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-05, 1402/02/15

Expected recruitment end date
2023-09-21, 1402/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the efficacy of new arthiculated AFO on biomechanical parameters in gait of multiple sclerosis

Public title
Efficacy of Ankle Foot Orthosis on Multiple Sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

At least 6 months after diagnosed with MS Extended disability scale between 4 to 6 Unilateral drop foot Endurance to ambulate at least 30 feet continuously with minimal assist without the use of an AFO The maximum spasticity of grade II with plantar flexor muscles according ti Ashworth scale

Exclusion criteria:

Significant cardiac or respiratory disease Musculoskeletal impairments and/or pain that severely limited walking Fixed flexion contracture or spasticity of the hip, knee and ankle joints History of surgery, trauma, and fracture in lower limbs

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

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 committe 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

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6517838736

Approval date

2022-12-10, 1401/09/19

Ethics committee reference number

IR.UMSHA.REC.1401.781

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple Sclerosis

Primary outcomes

1

Description

Biomechanical parameters (spatiotemporal, kinematic and kinetic)

Timepoint

Before intervention and after intervention

Method of measurement

Motion analysis system and force plate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Newly designed spring damper Ankle Foot Orthosis

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

The biomechanical laboratory of the Movaghian Research Centre of Intelligent Neuro-Rehabilitation Te

Full name of responsible person

Ensieh Pourhoseingholi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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 professor
Latest degree
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Person responsible for updating data

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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
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
Yes - There is 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
Title and more details about the data/document
Spatiotemporal parameters (speed of walking, cadence, step and stride length, step and stride time) Kinematic parameters (angle of hip, knee and ankle joint) Kinetic parameters (power and moment of hip, knee and ankle joint)
When the data will become available and for how long
Start of access period from 1403
To whom data/document is available
Researchers
Under which criteria data/document could be used
Research in health service system
From where data/document is obtainable
Ensieh Pourhoseingholi, Hamadan University of Medical Science
What processes are involved for a request to access data/document
After publication from Email
Comments