

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigating the efficacy of new articulated 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 sclerosis

##### 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

###### Email address

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 articulated 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 to 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 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**

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

**Street address**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Ensieh Pourhoseingholi  
**Street address**  
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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**  
Orthosis and Prosthesis  
**Street address**

## Person responsible for scientific 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**  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
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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