# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The comparison of the immediate effects of UD-Flex and PLS orthoses on spatiotemporal gait parameters in individuals with Multiple Sclerosis and Drop foot: A randomized crossover clinical study

## Protocol summary

**Study aim**

Comparison of the immediate effect of UD-Flex and PLS orthoses on spatiotemporal gait parameters in individuals with multiple sclerosis and foot drop

**Design**

A randomized,single-blind,cross-over clinical trial with 12 participants

**Settings and conduct**

Samples will be selected from available individuals with multiple sclerosis and foot drop at the outpatient clinics of Kashani Hospital, Isfahan, Iran. Blinding of the participants was not possible because they could see which intervention they were wearing.By coding the data, the data analyst was blinded. To prevent assessment bias, automated devices were used to measure the gait variables.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Individuals with multiple sclerosis and foot drop with disability score between 4 and 6 and able to walk without the assistance of a device or another person. Exclusion Criteria: Individuals who have had a relapse (exacerbation) of the disease within the past 3 months as confirmed by a physician. Individuals with impaired consciousness who cannot provide informed consent. Musculoskeletal disorders that impair the individual's walking. Individuals with severe cardiac or respiratory problems that prevent the patient's participation and the performance of tests.

**Intervention groups**

Intervention1: Custom-made PLS ankle-foot orthosis fabricated at the Orthotics and Prosthetics Clinic of Kashani Hospital, Isfahan, Iran, for each patient.It is placed behind the calf and ankle, and the heel has no contact with the ground.Intervention2: Prefabricated UD-Flex orthosis from ADVANFIT INC, Japan,placed in front of the ankle,with the heel having direct contact with the ground.Control:Barefoot (without orthosis).A 10-minute rest period is provided between each test to ensure that fatigue does not affect the results.

**Main outcome variables**

Cadence,Walking speed,Step length,step width,Double support time

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20231209060299N1**
Registration date: **2026-05-29, 1405/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-29, 1405/03/08**
Update count: **0**

**Registration date**

2026-05-29, 1405/03/08

**Registrant information**

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Hossein Asiaemehr
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2026-05-21, 1405/02/31

**Expected recruitment end date**

2026-05-31, 1405/03/10

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The comparison of the immediate effects of UD-Flex and PLS orthoses on spatiotemporal gait parameters in individuals with Multiple Sclerosis and Drop foot: A randomized crossover clinical study

**Public title**
The effect of orthoses on gait in individuals with multiple sclerosis and foot drop.
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
People with relapsing-remitting multiple sclerosis who are in the remission phase. individuals with drop foot. Maximum spasticity in the ankle plantar flexor muscles should be grade 2 according to the Modified Ashworth Scale (MAS). The patient's disability score should be between 4 and 6. Patients aged 20–50 years. The individual should be able to walk 20 meters without assistance from others or with the use of a walking aid.
**Exclusion criteria:**
Individuals who have had a relapse (exacerbation) of the disease within the past 3 months, as confirmed by a physician. Individuals with impaired consciousness who cannot provide informed consent. Musculoskeletal disorders that impair the individual's walking. Individuals who have severe cardiac or respiratory problems that prevent the patient's participation and the performance of the tests. History of fractures or surgeries of the lower limbs, ankle sprain, osteoarthritis, and pain that severely limits walking. Individuals with psychiatric disorders.
**Age**
From **20 years** old to **50 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **12**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization method in this study was simple randomization. Due to the cross-over design and the random order of all three conditions (barefoot, PLS orthosis, and UD-Flex orthosis), simple randomization was used to determine the sequence of testing. Given the limited sample size (12 participants) and the absence of different subgroups, block or stratified randomization methods were not required, and there were no randomization layers. The unit of randomization was the individual, and each participant independently received their own sequence of interventions. Each of the 6 possible sequences (3!) was written on cards and placed inside opaque, non-visible envelopes. The envelopes were numbered and sealed by an individual independent of the researcher. The random sequence was generated using a random number table by a person independent of the researcher before the start of the study. Considering the three conditions (barefoot, PLS orthosis, UD-Flex orthosis) and the completely random order of their execution, all 6 possible permutations (3!) were considered equally likely. For each participant, a two-digit random number was selected from the random number table, and based on the remainder of division by 6 (0 to 5), one of the 6 sequences was randomly determined. Allocation concealment was performed using opaque, sealed, sequentially numbered envelopes. The researcher was unaware of the sequence of conditions until the time of testing and opening the envelope corresponding to each patient. After recording the patient's characteristics and confirming the inclusion criteria, the corresponding envelope was opened in numerical order, and the test sequence was executed according to the envelope's contents. This method prevented bias in the allocation of intervention order. An important point is that the barefoot condition was considered the control condition (without intervention), and the randomization of its order did not change its control nature. A 10-minute rest period was provided between different tests to eliminate fatigue and carryover effects.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Since all participants are assessed under all three conditions (and are not divided into intervention and control groups), it is not possible to blind the participants or the assessor. To maintain single blinding, the data analyst will be unaware of how the intervention (type of orthosis) was allocated in each test session. For this purpose, all raw data collected by the motion analysis system will be coded before being delivered to the analyst, so that they will not be able to identify the type of intervention.
**Placebo**
Not used
**Assignment**
Crossover
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Nursing, Rehabilitation & Management schools- Isfahan

**Street address**
School of Rehabilitation, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan
**City**
Isfahan
**Province**
Isfehan
**Postal code**
8174673461
**Approval date**
2026-04-18, 1405/01/29
**Ethics committee reference number**
IR.MUI.NUREMA.REC.1405.005

## Health conditions studied

### 1

**Description of health condition studied**
Foot drop in multiple sclerosis
**ICD-10 code**
G35
**ICD-10 code description**
Multiple sclerosis

## Primary outcomes

### 1

**Description**
Cadence
**Timepoint**
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
**Method of measurement**
Qualisys motion capture system

### 2

**Description**
Walking speed
**Timepoint**
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
**Method of measurement**
Qualisys motion capture system

### 3

**Description**
Step length
**Timepoint**
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
**Method of measurement**
Qualisys motion capture system

### 4

**Description**
Step width
**Timepoint**
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
**Method of measurement**
Qualisys motion capture system

### 5

**Description**
Double support time
**Timepoint**
Measurements are performed randomly under three conditions: barefoot, immediately after wearing the PLS orthosis following a 5-minute accommodation period, and immediately after wearing the UD-Flex orthosis following a 5-minute accommodation period. All measurements are conducted in a single session to assess the immediate effect, and there is no follow-up period (daily or weekly). The assessment frequency is only once per condition.
**Method of measurement**
Qualisys motion capture system

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention Group 1: PLS orthosis; a type of ankle-foot orthosis placed on the posterior side of the calf and ankle, custom-made for each patient at the Orthotics and

Prosthetics Clinic of Kashani Hospital, Isfahan, Iran. This orthosis is made of thermoplastic polypropylene material. It also has a non-slip rubber footplate and is worn without shoes. After putting on the orthosis, the participant walks along a 7-meter path, and their movements are recorded by a motion analysis system. It is worth noting that the effect of the orthosis is immediate and short-term, and its effect disappears as soon as the orthosis is removed. Nevertheless, a 10-minute rest period is provided between different tests to eliminate fatigue and carryover effects.

**Category**

Rehabilitation

**2**

**Description**

Intervention Group 2: UD-Flex orthosis; a prefabricated orthosis manufactured by ADVANFIT INC., Japan, which is placed on the anterior side of the ankle, allowing the heel to freely contact the ground during walking. After precise measurement of each patient's foot dimensions (foot length, foot width, and calf circumference), the appropriate orthosis size is selected from the available standard sizes based on the manufacturer's sizing chart. The individual wears this orthosis without shoes. After donning the orthosis, the participant walks along a 7-meter path, and their movements are recorded by a motion analysis system. It is worth noting that the effect of the orthosis is immediate and short-term, and its effect disappears as soon as the orthosis is removed. Nevertheless, a 10-minute rest period is provided between different tests to eliminate fatigue and carryover effects.

**Category**

Rehabilitation

**3**

**Description**

Control Group: Barefoot (without orthosis); the barefoot condition is considered the control condition (without intervention), in which the participant walks barefoot along a 7-meter path, and their movements are recorded by a motion analysis system. A 10-minute rest period is provided between different tests to eliminate fatigue and carryover effects.

**Category**

N/A

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ayatollah Kashani Educational and Medical Center, Isfahan

**Full name of responsible person**

Dr.Vahid Shaygannejad

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Ayatollah Kashani Educational and Therapeutic Center (Jouzdan Neighborhood), Ayatollah Kashani Miyani Street, Mirdamad, Isfahan, Iran

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr.Gholamreza Asgari

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Building No. 4, Vice Chancellery for Research and Technology, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

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askari@mui.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**
Dr.Hossein Asiyaeimehr

**Position**
Assistant Professor and Faculty Member of the Department of Orthotics and Prosthetics

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Orthotics and Prosthetics

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## Person responsible for scientific inquiries

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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

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**Latest degree**
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**Other areas of specialty/work**
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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**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
Study data (excluding personal information) will be shared with other researchers.

**When the data will become available and for how long**
The data will be shared after the publication of the results or a summary of the data.

**To whom data/document is available**
The data will be shared solely for academic purposes.

**Under which criteria data/document could be used**
The data will be shared for teaching and research purposes of the applicants.

**From where data/document is obtainable**
Individuals can request the information from the designated responsible person.

**What processes are involved for a request to access data/document**
Requests must be sent via email (asiyaeimehr@rehab.mui.ac.ir).

**Comments**