Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Immediate effect of rocker shoes on balance and temporo-spatial parameters of gait in subjects with multiple sclerosis with drop foot, volunteer for using flexible ankle orthosis

Protocol summary

Study aim

The effect and evaluation of rocker shoes on balance and temporo-spatial parameters in subjects with multiple sclerosis with drop foot, volunteer for using flexible ankle orthosis

Design

This study is a prospective, before and after, interventional study. Ten patients with multiple sclerosis who are under the supervision of Isfahan multiple sclerosis association are examined and evaluated by a neurologist. Neurological examination will be performed using the Extensive Disability Scoring Criteria (EDSS), which is the most common tool for measuring inflammatory disability.

Settings and conduct

The site of study is the musculoskeletal center of Isfahan University of Medical Sciences. The study is one-sided blind. The patient does not know the type of intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18-50 years; The degree of disability is moderate and the EDSS score is in the range of 3.0-6.0; Can walk at least 30 feet independently or with the help of a cane; Weakness in the dorsiflexor muscles of the ankle (drop foot); The score of the modified Assyrian scale is less than 2. Non-inclusion criteria: Exacerbation of MS in the last 3 months; Prescribing drugs for fatigue or mobility such as phamperidine, amantadine; Severe heart or respiratory problems; Musculoskeletal disorders or severe pain that prevents walking

Intervention groups

In this study, we use PLS orthosis and rocker sole to control the foot drop and promote of their gait parameters.

Main outcome variables

Balance; Temporo-spatial parameters of gait

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047459N3**
Registration date: **2020-11-02, 1399/08/12**
Registration timing: **retrospective**

Last update: **2020-11-02, 1399/08/12**
Update count: **0**

Registration date

2020-11-02, 1399/08/12

Registrant information

Name

Masoud Rafiaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 5043

Email address

ma.rafiaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

2020-06-21, 1399/04/01

Actual recruitment end date

2020-08-21, 1399/05/31

Trial completion date

2020-09-21, 1399/06/31

Scientific title
Immediate effect of rocker shoes on balance and temporo-spatial parameters of gait in subjects with multiple sclerosis with drop foot, volunteer for using flexible ankle orthosis

Public title
Effect of rocker shoes on balance and gait parameters in subjects with multiple sclerosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 18-50 years The disability rate is moderate and the EDSS score is in the range of 3.0-6.0 Can walk at least 30 feet independently or with the help of a cane. Weakness in the dorsiflexor muscles of the ankle (drop foot) The score of the modified Assyrian scale is less than 2

Exclusion criteria:
Exacerbation of MS in the last 3 months Prescribing medications for fatigue or mobility such as phamperidine, amantadine Severe heart or respiratory problems Musculoskeletal disorders or severe pain that prevents walking

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**
Actual sample size reached: **10**

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
Ethics commitee of Isfahan University of Medical Sciences

Street address
Rehabilitation college, Hezarjerib street

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2020-04-24, 1399/02/05

Ethics committee reference number
IR.MUI.RESEARCH.REC.1399.091

Health conditions studied

1

Description of health condition studied
Multiple Sclerosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Balance: The center of gravity of an object can be considered as the equilibrium point of that object. If all the forces acting on a part are in balance, that object is at rest or moving steadily.

Timepoint
before and after intervention

Method of measurement
force plate

2

Description
number of steps per minute,

Timepoint
before and after intervention

Method of measurement
Camera

3

Description
walking speed,

Timepoint
before and after intervention

Method of measurement
Camera

4

Description
stride length

Timepoint
before and after intervention

Method of measurement
Camera

5

Description
static phase percentage
Timepoint
before and after intervention
Method of measurement
Camera

Secondary outcomes

empty

Intervention groups

1

Description
In this study, 10 subjects walk on a path 13 meters long and 3 meters wide at their chosen speed. Information is provided by infrared cameras located in the laboratory environment that are sensitive to markers installed on the body. Each person will first perform the experiment with PLS orthosis, which covers the foot and ankle area and shoes without rollers, then rest for 10 minutes and perform the experiment with PLS with roller shoes.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan MS Association
Full name of responsible person
Masoud Rafiaei
Street address
Hezarjerib
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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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
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
Masoud Rafiaei
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Orthopedics
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Full name of responsible person

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable