

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 committee of Isfahan University of Medical Sciences

Street address

Rehabilitation college, Hezarjerib street

City

Isfahan

Province

Isfahan

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

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Hezarjerib

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

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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Person responsible for scientific inquiries

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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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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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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)

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