

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The immediate effects of using an ankle-foot orthosis and a Dictus-band on the the gait and balance of people with Multiple Sclerosis

Protocol summary

Study aim

To compare the immediate effects of ankle-foot orthosis and Dictus-band on the gait and balance of people with multiple sclerosis

Design

This is a crossover clinical trial. The sample size was determined based on the previous similar studies and set at 15 participants. The gait of all participants (in a single group) were tested in three conditions: with an ankle-foot orthosis, with dictus-band, and barefoot.

Settings and conduct

There was a convenience sampling method. Participants were recruited from outpatient clinics of Alzahra hospital, Isfahan, Iran. Blinding of participants was not possible as they could see what they worn. Automated measurements were used to prevent assessment bias in the balance and gait testing.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the expanded Disability Status Scale (EDSS) between 3 to 6, walking ability without assistance of a device or person. Exclusion criteria: history of the relapse in the last three months, inability to give an informed consent due to cognitive problems, musculoskeletal conditions that affect the gait, curdio-pulmonary problems that could prevent the testing, and having severe depression (Beck score>40).

Intervention groups

Intervention 1: a static ankle-foot orthosis that restricts plantar flexion. Intervention 2: a soft dynamic orthosis is called Dictus-Band that assists dorsi flexion at the ankle. Control: barefoot (without orthosis).

Main outcome variables

Postural stability; speed in 10 meter walking test; Forward reach test; "get up and go" test time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150210021034N8**

Registration date: **2020-03-31, 1399/01/12**

Registration timing: **retrospective**

Last update: **2020-03-31, 1399/01/12**

Update count: **0**

Registration date

2020-03-31, 1399/01/12

Registrant information

Name

Ebrahim Sadeghi-Demneh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-06-09, 1395/03/20

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

2017-04-30, 1396/02/10

Actual recruitment end date

2017-08-21, 1396/05/30

Trial completion date

2017-08-21, 1396/05/30

Scientific title

The immediate effects of using an ankle-foot orthosis and a Dictus-band on the the gait and balance of people with Multiple Sclerosis

Public title

Effects of othoses on the gait of people with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The Expanded Disability Status Scale (EDSS) between 3 to 6 Participants could walk without assistance of a device or person

Exclusion criteria:

People with a history of relapse in the last three month
People with cognitive problem who could not give an informed consent
Musculoskeletal conditions which affect the gait
People with severe cardio-pulmonary problems which could prevent the testing
People with severe depression (Beck score>40)

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **15**

Actual sample size reached: **15**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical committee of Isfahan University of Medical Sciences, Isfahan, Iran

Street address

Hezar Jerib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2015-05-26, 1394/03/05

Ethics committee reference number

IR.MUI.REC.1394.3.979

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**

Postural stability

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured 10 minutes after receiving trial conditions.

Method of measurement

Participants were asked to stand quiet on the measurement equipment (force-plate) whilst put the feet together and keep the arms relaxed beside the body.

The center of pressure was recorded during 60 second of standing.

2**Description**

speed in 10 meter walking test

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured 10 minutes after receiving trial conditions.

Method of measurement

Participants were asked to walk in a 10 meter path then time recorded with a stopwatch and speed of walking was calculated.

3**Description**

Forward reach test

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured 10 minutes after receiving trial conditions.

Method of measurement

Participants stood with feet together and raised the arm at their shoulder level then leaning forward as much as could with heels in contact with the ground. The anterior displacement of the hand was measured using a yardstick or tape.

4**Description**

"get up and go" test time

Timepoint

All intervention was allocated in a straight forward session and outcomes were measured 10 minutes after receiving trial conditions.

Method of measurement

Participants sat on a chair to start the test. They get up with a "go" signal and walk until reach a line at 3 meters distance from the chair then turned and walk back to the chair and sit on it. The time was recorded using a stopwatch.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention: ankle-foot orthosis, was a custom-made orthosis. this was a thermoplastic polypropylene orthosis. The footplate of orthosis covered with an anti-slipping rubber and was used without shoes. After fitting the orthosis, participant walk in a five-meter walkway and a motion analyzer system records their movements.

Category

Rehabilitation

2

Description

Second intervention: Dynamic orthosis (dictus-band); consisted of a leg band, a foot band and a connecting rubber band. This orthosis was fitted based on the participant's size. After fitting the orthosis, participant walk in a five-meter walkway and a motion analyzer system records their movements.

Category

Rehabilitation

3

Description

Control: barefoot (without orthosis); participants walk in a five-meter walkway and a motion analyzer system records their movements.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital, Isfahan, Iran

Full name of responsible person

Masoud Etemadifar

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Sofeh boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahdi Nematbakhsh

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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

Ebrahim Sadeghi-Demneh

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthopedics

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be 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

The study data (excluding the personal details) can be shared with other researchers or systematic reviewers.

When the data will become available and for how long

No specific limitation is considered.

To whom data/document is available

No limit was set.

Under which criteria data/document could be used

No terms and conditions is considered for sharing the data.

From where data/document is obtainable

People can send their request to the correspondence and obtain the data.

What processes are involved for a request to access data/document

Request can be sent through an email.

Comments