

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of Rocker bar shoes on rocker function in hemiplegic patients walking with Ankle Foot Orthosis

Protocol summary

Summary

Objectives:The aim of this study is to evaluate the effect of Rocker shoes on rocker function in hemiplegic patients walking with Ankle Foot Orthosis (AFO). **Design:** twenty post-stroke hemiplegic patients aged between 45-70 (men and women) will participate in present study. They will be randomly selected from patients referred to rehabilitation centers of Hamadan. **Setting and conduct:** Patients will be present at the test center two times. At the first time their lower extremity will be examined to prepare rocker shoes, standard shoes and AFO for them. At the second session, the shoes and AFO will be delivered to the patients, and then, the immediate effect of each type of shoes on plantar forces and pressures and self selected speed will be evaluated by pedar system while participants walking with AFO. **Participants:** The inclusion criteria for the participants of the presents study is being at least six months post-stroke; having the ability of walking for 10 meters independently and having maximum spasticity of 2 according to Modified Ashworth Scale. **Intervention:** Interventions includes Rocker shoes, Standard shoes and AFO. **Main outcome measures:** Heel Mean Force, Toe Mean Force, Heel Impulse, Toe Impulse, Single Support time, Preferred Walking Speed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103124802N1**
Registration date: **2016-01-27, 1394/11/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-27, 1394/11/07

Registrant information

Name

Farzad Farmani

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1037

Email address

f.farmani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-07-01, 1395/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rocker bar shoes on rocker function in hemiplegic patients walking with Ankle Foot Orthosis

Public title

The effect of rocker shoes on walking with ankle foot orthosis in patients with hemiplegia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria Having the spasticity score of 3 or more according to Modified Ashworth Score; Having the ability of walking at least 10 meters independently; Being at

least 6-month post stroke. Exclusion criteria: Having cardiovascular problem; Having any history of surgery in their spine and lower limbs; Lack of the ability to perform the tests.

Age

From **45 years** old to **70 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomized block design was used for randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh Blvrd.

City

Hamadan

Postal code

6517838736

Approval date

2015-10-17, 1394/07/25

Ethics committee reference number

IR.UMSHA.REC.1394.313

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Heel mean force

Timepoint

Immediate effect

Method of measurement

By Pedar system

2

Description

Heel impulse

Timepoint

Immediate effect

Method of measurement

By Pedar system

3

Description

Toes mean force

Timepoint

Immediate effect

Method of measurement

By Pedar system

4

Description

Toes impulse

Timepoint

Immediate effect

Method of measurement

By Pedar system

5

Description

Single support time

Timepoint

Immediate effect

Method of measurement

By Pedar system

6

Description

Preferred walking speed

Timepoint

Immediate effect

Method of measurement

10-meter walk test

Secondary outcomes

empty

Intervention groups

1

Description

Standard shoes : Includes a pair of high top shoes whose soles are almost flat with the height of 2-cm. They will be used along with Ankle Foot Orthosis.

Category

Treatment - Devices

2

Description

Rocker shoes which includes a pair of high top shoes that their outsole from heel to just proximal to the metatarsal heads are flat. Rocker modification is started from metatarsal heads to the tip toes portion. The height of sole is 2-cm and will be used along with Ankle Foot Orthosis.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Farzad Farmani

Street address

Shahid fahmideh blvrd.

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Ali Abdoli

Street address

Shahid fahmideh blvrd.

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Farzad Farmani

Position

Assistant professor/Ph.D

Other areas of specialty/work

Street address

Shahid fahmideh Blvrd.

City

Hamadan

Postal code

6517838736

Phone

+98 81 3838 1571

Fax

+98 81 3838 1572

Email

Farmani.farzad@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Farzad Farmani

Position

Assistant professor/Ph.D

Other areas of specialty/work

Street address

Shahid fahmideh blvrd

City

Hamadan

Postal code

6517838736

Phone

+98 81 3838 1571

Fax

+98 81 3838 1572

Email

farmani.farzad@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Farzad Farmani

Position

Assistant professor/Ph.D

Other areas of specialty/work

Street address

Shahid fahmideh Blvrd.

City

Hamdan

Postal code

6517838736

Phone

+98 81 3838 1571

Fax

+98 81 3838 1572

Email

farmani.farzad@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty