Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 too 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

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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 critera: 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 commitee 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 supprot 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 hight 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
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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
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Shahid fahmideh blvrd.
City
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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
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
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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