Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The efficiency of articulated ankle-foot orthosis with first and second rockers mechanism and rocker sole shoe on walking biomechanics in patients with hemiplegic stroke: Randomized Clinical Trial

Protocol summary

Study aim

Effect of an AFO with plantarflexion resistance (for improving first and second rockers) and rocker sole shoe (for improving the third rocker) on gait parameters of stroke patients.

Design

The present study is a randomized, parallel-group controlled trial. The study group (n=10) will receive an articulated AFO with resistance to plantarflexion (AFO-PR) with 2 shoes types (standard shoe and rocker shoe), and the control group (n=10) will receive a conventional articulated AFO with plantarflexion stop (AFO-PS) with 2 shoes types (like study group). Blinding of patients or therapists was not possible in all articles because of the nature of the intervention

Settings and conduct

1. University of Social Welfare and Rehabilitation Science, Iran, Tehran 2. Dr. jawad Mowafaghian Research Center for Intelligent NeuroRehabilitation Technologies, Sharif University of Technology

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Stroke patients should have plantarflexors spasticity at least 2 according to the modified Ashworth scale -A minimum of 6 months post stroke Exclusion criteria: A fixed contraction in the ankle hip and knee joints Patients with knee hyperflexion Very poor balance based on TUG test

Intervention groups

Study group: articulated AFO with plantarflexion resistance control group: conventional articulated AFO with plantarflexion stop

Main outcome variables

Walking parameters including: 1.Temporal-spatial parameters (walking speed, step length, stride length, cadence) 2. Walking Kinematic (sagittal joints angles of ankle, knee and hip, and pelvic 3-dimensional angles in pelvis and thorax) 3. Walking Kinetic (sagittal joints moments of ankle, knee and hip, anterior-posterior ground reaction force).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190625044003N1**
Registration date: **2019-09-12, 1398/06/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-09-12, 1398/06/21**
Update count: **0**

Registration date

2019-09-12, 1398/06/21

Registrant information

Name

Aliyeh Daryabor

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficiency of articulated ankle-foot orthosis with first and second rockers mechanism and rocker sole shoe on walking biomechanics in patients with hemiplegic stroke: Randomized Clinical Trial

Public title

The efficiency of articulated ankle-foot orthosis and rocker sole shoe on walking biomechanics in stroke patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40 to 68 Stroke patients should have plantarflexors spasticity at least 2 according to the modified Ashworth scale (MAS) A minimum of 6 months poststroke No involvement in the contralateral limb Able to walk independently Patients should have the passive ability to dorsiflex ankle joint

Exclusion criteria:

The presence of hammered toes, Fixed contraction in the ankle, hip and knee joints, Having a history of cardiovascular and pulmonary disease Patients with knee hyperflexion Very poor balance based on TUG test

Age

From **40 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the sampling method in the present study is consecutive. It means that researcher gets present at the patients' referral site (Dr. Jawad Mowafaghian Research Center for Intelligent NeuroRehabilitation Technologies) from the beginning of the study, and patients who are eligible to participate in the study are identified and then, invited to participate in the study. Therefore, randomization is occurred consecutively. It should be noted that only one rehabilitation center is sampled in this study. In this study, simple randomization method is used and randomization unit is individual. In this way, participants with the odd number assigned to them (By order of referral) are included in the intervention group, and participants with the even number assigned to them are included in the control group. The allocation concealment is that Participants are unaware of the allocation of groups (intervention and control group).

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants (patients) are unaware of the allocation of groups (intervention group and control group). That is, participants are unaware of which group, intervention group, and which group is the control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Science

Street address

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Tehran

Postal code

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Approval date

2016-12-02, 1395/09/12

Ethics committee reference number

IR.USWR.REC.1395.399

Health conditions studied

1

Description of health condition studied

cerebrovascular accident (stroke)

ICD-10 code

G46.3*

ICD-10 code description

Brain stem stroke syndrome

Primary outcomes

1

Description

Temporal-spatial parameters (walking speed, step length, stride length, cadence)

Timepoint

In this study, after fabrication of orthoses for patients, the subjects use the made orthosis for adapting in daily living for 2 weeks. Then, patients refer to gait biomechanics laboratory, and gait parameters are measure in two condition, without orthosis and with orthosis

Method of measurement
Three-dimensional movement capture system (vicon)

2

Description
Walking Kinematic (sagittal joints angles of ankle, knee and hip, and pelvic 3-dimensional angles in pelvis and thorax)
Timepoint
In this study, after fabrication of orthoses for patients, the subjects use the made orthosis for adapting in daily living for 2 weeks. Then, patients refer to gait biomechanics laboratory, and walking Kinematic are measure in two condition, without orthosis and with orthosis
Method of measurement
Three-dimensional movement capture system (vicon)

3

Description
Walking Kinetic (sagittal joints moments of ankle, knee and hip, anterior-posterior ground reaction force).
Timepoint
In this study, after fabrication of orthoses for patients, the subjects use the made orthosis for adapting in daily living for 2 weeks. Then, patients refer to gait biomechanics laboratory, and walking Kinetics are measure in two condition, without orthosis and with orthosis.
Method of measurement
Kistler forceplate

Secondary outcomes

1

Description
Fatigue during walking with orthoses
Timepoint
In this study, after fabrication of orthoses for patients, the subjects use the made orthosis for adapting in daily living for 2 weeks. Then, patients refer to gait biomechanics laboratory, and fatigue variable are measure in two condition, without orthosis and with orthosis by the questionnaire.
Method of measurement
Questionnaire

Intervention groups

1

Description
Intervention group: ankle foot orthosis (AFO) with plantar flexion resistance and 2 kind of shoes (standard shoe and rocker shoe)
Category
Rehabilitation

2

Description
Control group: Intervention group: ankle foot orthosis (AFO) with plantar flexion resistance and 2 kind of shoes (standard shoe and rocker shoe)
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Djawad Mowafaghian Research Center for Intelligent NeuroRehabilitation Technologies
Full name of responsible person
Dr. Farzam Farahman and Dr. Saeid Behzadipour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran National Science Foundation
Full name of responsible person
Dr. Iman Eftekhari
Street address
No 3, fifth alley, above the junction of Jalal Al Ahmad, North Kargar Street
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Web page address
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Grant name

Grant code / Reference number
95849762
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
University of social welfare and rehabilitation sciences
Full name of responsible person
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All above will be published in the article
When the data will become available and for how

long

After the article publication

To whom data/document is available

After the article publication, people can access

Under which criteria data/document could be used

Other researchers and therapists in the rehabilitation and medical field can use this use the data of this study after the article publication

From where data/document is obtainable

After the article publication, people can find the article by searching in internet and access the data

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

After the article publication, people can find the article by searching in internet and access the data

Comments