Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Clinical trial of Comparing the immediate effect of both conventional and neoprene modified polypropylene ankle foot orthosis on kinematic parameters of gait in people with foot drop syndrome

Protocol summary

Summary

Objectives:The main objective of this study was to compare the immediate effects of two types of polypropylene ankle foot orthosis(afo); conventional and modified neoprene on the kinematic parameters of gait in people with drop foot syndrome and functional purpose of providing new approaches in the field of administration of orthosis for patients with drop foot syndrome. This study is a quasi-experimental intervention study. Study population: patients with drop foot syndrome. The inclusion criteria: participants, with a score of 0 or 1 ankle dorsiflexors; one-sided weakness of ankle dorsiflexors muscles, flaccid paralysis of the lower extremities following traumatic nerve injury, aged 25 to 50 years, the ability to walk without assistive devices for a period of 2 min. The exclusion criteria: any pain in the body, existing an open wound in the areas covered by the orthosis, obvious deformity in the lower extremities, disinclination to do more tests. Setting & conduct:the participants, were made to complete a consent form. Each person is expected to walk with both orthoses for 10 min. The tests will be taken 3 times: without orthosis, with solid afo and with neoprane afo changed on the dynamometer kystler, to evaluate the components of the kinetic gait movement. The best example will be selected. The data from these tests will be compared first together and then to the normal foot. Main out come measures: lower limb joint's angles; stance phase duration; swing phase duration

General information

Acronym

Ankle Foot Orthosis(AFO)

IRCT registration information

IRCT registration number: **IRCT2015120116810N3**

Registration date: **2016-05-05, 1395/02/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-05, 1395/02/16

Registrant information

Name

hassan saeedi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-01-23, 1394/11/03

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of Comparing the immediate effect of both conventional and neoprene modified polypropylene ankle foot orthosis on kinematic parameters of gait in people

with foot drop syndrome

Public title
Clinical trial of comparing the immediate effect of both conventional and neoprene modified polypropylene ankle foot orthosis on kinematic parameters of gait in people with foot drop syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
The main inclusion criteria were: participants, with a score of 0 or 1 ankle dorsiflexors which cause their foot to be dragged in swing phase, one-sided weaknessof ankle dorsiflexor muscles, flaccid paralysis of the lower extremities following traumatic nerve injury, aged 25 to 50 years, the ability to walk without assistive devices for a period of 2 min. The exclusion criteria were: any painfull pain in the body, existing an open wound in the areas covered by the orthosis, obvious deformity in the lower extremities, disinclination to do more tests.

Age
From **90 years** old to **66 years** old

Gender
Both

Phase
N/A

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of iran university of medical science

Street address
Iran university of medical science, Between Sheikh Fazlolah and Chamran Intersection, West Hemmat Highway, Tehran

City
Tehran

Postal code

Approval date
2015-06-17, 1394/03/27

Ethics committee reference number
IR.IUMS.REC.1394.9211502201

Health conditions studied

1

Description of health condition studied
DROP FOOT

ICD-10 code
M21.3

ICD-10 code description
(Wrist or foot drop (acquired

Primary outcomes

1

Description
Ankle joint angle

Timepoint
Immediate effect

Method of measurement
Using Kistler force plate and motion analyzer system in degrees

2

Description
Knee joint angle

Timepoint
Immediate effect

Method of measurement
Using Kistler force plate and motion analyzer system in degrees

3

Description
Hip joint angle

Timepoint
Immediate effect

Method of measurement
Using Kistler force plate and motion analyzer system in degrees

Secondary outcomes

1

Description
Step length

Timepoint
Immediate effect

Method of measurement
Using Kistler force plate in centimeters

2

Description
Stance during

Timepoint

Immediate effect

Method of measurement

Using Kistler force plate in second

3

Description

Swing during

Timepoint

Immediate effect

Method of measurement

Using Kistler force plate in second

Intervention groups

1

Description

Intervention group 1: drop foot people will walk while wearing modified neoprane orthose in their shoes on kistler force plate to predict the components of the kinetic and kinematic gait . The test process will be explained to the patient and they have to walk with both orthoses for 10 min . After being situated in the corresponding calibration the markers will be placed on bony landmarks and the person starts to walk. In order to detect the markers, the subject wore black trousers, nightwear and light reflective markers will be placed on the fifth metatarsal head, internal and external ankle, tubrasity of calcaneus, medial and latral condyle of femur for both feet. Even the study of the digital camera in the direction of movement is marked and moves will be recorded. The best example of the 3 modes will be selected. The data from these tests will be compared first together and then to the normal foot.

Category

Treatment - Other

2

Description

Intervention Group 2:The Test Will Be Taken While They'll Be Wearing Solid AFO With Their Shoes.

Category

Other

3

Description

Intervention Group 3: The Test Will Be Taken Barefoot

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Hassan Saeedi

Street address

School Of Rehabilitation Sciences, Maddadkaran Alley, Shahnazari Street, Mohseni Square, Mirdamad BLVD. , Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Iran University Of Medical Science

Full name of responsible person

Dr. Hassan Saeedi

Street address

School Of Rehabilitation Sciences, Maddadkaran Alley, Shahnazari Street, Mohseni Square, Mirdamad BLVD. , Tehran

City

Tehran

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 of Iran University Of Medical Science

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences and Health Services

Full name of responsible person

Dr. Hassan Saeedi

Position

Assistant Professor

Other areas of specialty/work

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School Of Rehabilitation Sciences, Maddadkaran Alley, Shahnazari Street, Mohseni Square, Mirdamad BLVD. , Tehran

City

Tehran

Postal code

Phone

+98 21 2222 8051

Fax

Email

Www.hassan_saeedi2@yahoo.co.uk

Web page address

Person responsible for updating data

Contact

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