Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparison between the immediate effects of Hip Flexion Assist Orthosis and conventional Ankle Foot Orthosis on gait parameters in ambulatory multiple sclerosis patients

Protocol summary

Summary

A comparison between the immediate effects of Hip Flexion Assist Orthosis (HFAO) and conventional Ankle Foot Orthosis (AFO) on gait parameters in ambulatory multiple sclerosis patients. Participants: Multiple sclerosis patients who were members of the Iran MS society and have met the inclusion: Acquiring 2 or 3 points in HA; Age between 20-45 years; Unilateral weakness in lower limb (flexor muscles); Ability of walking without any assistive devices for 2 minutes. Exclusion criteria: No pain; Any open wounds in waist area; Spasticity in the lower extremities; Any obvious deformity in the lower extremities. Sample size: 20. Intervention: AFO and HFAO. Duration of intervention: Almost 40 minutes for measuring the velocity and Symmetry variables. Dependent variables: Velocity, Symmetry, Satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206295520N7**
Registration date: **2012-09-17, 1391/06/27**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-09-17, 1391/06/27

Registrant information

Name

Mojtaba Kamyab

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

kamyab@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between the immediate effects of Hip Flexion Assist Orthosis and conventional Ankle Foot Orthosis on gait parameters in ambulatory multiple sclerosis patients

Public title

A comparison between the effects of Hip Flexion Assist Orthosis and conventional Ankle Foot Orthosis on walking in multiple sclerosis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Acquiring 2 or 3 points in HA; Age between 20-45 years; Unilateral weakness in lower limb (flexor muscles); Ability of walking without any assistive devices for 2 minutes. Exclusion criteria: No pain; Any open wounds in waist area; Spasticity in the lower extremities; Any obvious deformity in the lower

extremities.
Age
From **20 years** old to **45 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
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Rehabilitation, Tehran University of Medical Sciences
Street address
School of Rehabilitation, Shahnazari st, Mother Sq., Mirdamad Blvd.
City
Tehran
Postal code
Approval date
2012-01-30, 1390/11/10
Ethics committee reference number
1084/130/91/ɔ

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
Velocity
Timepoint
Just before the intervention and after 5 minutes.
Method of measurement
2MWT

2

Description
Satisfaction
Timepoint
After the interventions
Method of measurement
using the satisfaction questionnaire

3

Description
Symmetry of walking
Timepoint
Just before the intervention and after 5 minutes.
Method of measurement
Using Symetry Index

Secondary outcomes

empty

Intervention groups

1

Description
Hip Flexion Assist Orthosis
Category
Rehabilitation

2

Description
Conventional Ankle Foot Orthosis
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
The Iranian Multiple Sclerosis Society
Full name of responsible person
Street address
Iran MS Society, Shams Alley, Vesal St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Vice chancellor for research, Dr. Akbar Fotuhi
Street address
Rehabilitation faculty, Shah nazari st, Mohseni sq, Mirdamad blvd
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences, School of Rehabilitation.
Full name of responsible person
Mojtaba Kamyab
Position
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Other areas of specialty/work
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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