

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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
1084/130/91/3

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

Assistant prof / PhD

Other areas of specialty/work**Street address**

Orthotics & Prosthetics Dep., School of Rehabilitation,
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Position

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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