

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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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Full name of responsible person

Mojtaba Kamyab

Position

Assistant prof / PhD

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

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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