

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of the effects of functional electrical stimulation with and without ankle foot orthosis on balance and walking ability in multiple sclerosis using BESTest

Protocol summary

Study aim

Comparison of the effects of functional electrical stimulation with and without ankle foot orthosis on balance and walking ability in multiple sclerosis

Design

In the first step, to check the ability of the individual without the use of orthosis, all tests are performed and information is recorded. In the second stage, the participants are examined with Tiwan Functional Electrical Stimulation (T-102) and in the third stage the participants are tested with an ankle-foot orthosis equipped with Functional Electric Stimulation

Settings and conduct

. Refer to MS Medical Centers in Tehran and review the existing records of individuals. At first, the objectives, methods and other information needed will be provided to the subjects. Individuals are assessed for personal and physical information by diagnosing drop foot. People who do not meet the inclusion criteria will leave the study.

Participants/Inclusion and exclusion criteria

Individuals with MS score less than five on the EDSS index
Patients with multiple sclerosis have at least three months
People with relative walking ability without the use of assistive devices
Experience using ankle-foot orthoses or functional electrical stimulation, or both

Intervention groups

Patients with MS with foot drop may use electric stimulation devices or orthoses such as ankle foot orthoses, which are used to prevent toe dragging during the swing phase. An alternative approach is to stimulate the peroneal nerve involved in MS disease by electrical stimulation system. This nerve is essential for the production of dorsiflexion during the swing phase. An electrical stimulation system is a system that uses short pulses and electrical bursts to generate muscle contraction.

Main outcome variables

Walking ability, stability, biomechanical limitations, balance ability, walking speed and ability to change position

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200301046657N1**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Ali Khaghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-15, 1398/12/25

Expected recruitment end date

2020-05-03, 1399/02/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of functional electrical stimulation with and without ankle foot orthosis on balance and walking ability in multiple sclerosis using BESTest

Public title

Comparison of the effects of functional electrical stimulation in multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

People with MS scores below five on the EDSS index
Patients with multiple sclerosis who have drop foot at least three months
People with walking ability without use of assistive devices
Ability to walk and stand for at least three minutes
Experience using ankle-foot orthoses or functional electrical stimulation, or both
Patient satisfaction to participate in the study
Ability to read and write in Farsi

Exclusion criteria:

History of surgery and fractures in the lower extremities
History of lower extremity trauma
Inappropriate postures such as kyphosis and scoliosis
Infection and inflammation of the skin in the calf region
The progression of MS is so debilitating for the individual
Dryness and immobility of the ankle joint
Contraction in the calf muscles
Short back muscles and tendons in the calf
Severe lower limb muscle spasms that affect ankle joint movements
Any abnormalities and deformities in the joints and bones of the foot and ankle
People who need help moving from others or using assistive devices

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: **28**

Randomization (investigator's opinion)

N/A

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 Sciences

Street address

Hemat Highway next to Milad Tower, Iran University of Medical sciences

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.IUMS.REC.1398.1363

Health conditions studied**1****Description of health condition studied**

Patients involved with multiple sclerosis with drop foot

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The effect of functional electrical stimulation on balance in patients with MS with ankle deprivation

Timepoint

Immediate examination before and after wearing orthoses

Method of measurement

Using tests of BESTest

2**Description**

The effect of using ankle-foot orthosis equipped with functional electrical stimulation on balance in patients with MS

Timepoint

Immediate examination before and after wearing orthoses

Method of measurement

Using tests of BESTest

3

Description

The effect of functional electrical stimulation on walking ability in patients with MS

Timepoint

Immediate examination before and after wearing orthoses

Method of measurement

Using tests of BESTest

4

Description

The effect of using ankle-foot orthoses equipped with functional electrical stimulation on walking ability in people with MS

Timepoint

Immediate examination before and after wearing orthoses

Method of measurement

Using tests of BESTest

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To help clear the foot we stimulate the peroneal nerve involved in MS disease by electrical stimulation system. This nerve is essential for producing dorsiflexion during the swing phase. The peroneal nerve can also initiate reflex synergistic-based flexion, thereby enhancing hip and knee flexion during the swing gate phase. An electrical stimulation system is a system that uses short pulses and electrical bursts to generate muscle contraction. If these electrical pulses are applied to the motor nerves, it can cause action potentials that extend along the axon to the target muscle, and when this action potential reaches the target muscle, the muscle contracts

Category

Rehabilitation

2

Description

Intervention group: Patients with MS with ankle sprains use orthoses such as the foot-orthosis (AFO), which is used to prevent patients from colliding with the ground during the swinging walk. The orthosis is made of hard plastic and extends from the joint between the bones of the foot and toes to the top of the leg. Ankle-foot orthosis alone is used for people with good leg muscles to move in an upright position. When the patient has dorsiflexion, the orthosis prevents the fingers from touching the ground. If the patient has sufficient knee strength, an adjustable wrist joint may be used in the orthosis, which allows for dorsiflexion and enhances the ease of

functional activity. Acceptance of ankle-foot orthosis in these patients is very poor. Weight, appearance or lack of response to patients' needs are the reasons for not using this orthosis.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Rehabilitation, Iran University of Medical Sciences

Full name of responsible person

Dr. Alireza Khaghani

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Faculty of Rehabilitation Sciences., Maddekaran St., Shah Nazari St., Mirdamad, Mother Square

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

علیرضا خاقانی

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All data can be shared after unidentifiable people

When the data will become available and for how long

Starting one year after article publication

To whom data/document is available

Information is available to all researchers working in academic and scientific institutions

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article

From where data/document is obtainable

connect to Dr Alireza Khaghani by email:
Khaghaniali@yahoo.com

What processes are involved for a request to access

data/document

If information is used in scientific and therapeutic activities, information is provided as soon as possible.

Comments