Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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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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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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 ib scintific and therapeutic activities, information is provided as soon as possible.

Comments