

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparative Effects of Dry Needling of Gastrocnemius -Soleus muscles on Neuromodulation, Spasticity, and Balance in patients with MS (relapsing-remitting) and stroke

Protocol summary

Study aim

Comparison of the effects of dry needling of gastrocnemius and soleus muscles on nerve modulation, spasticity, and balance in patients with MS (relapsing-recovering type) and stroke

Design

The prospective clinical trial, parallel-group trial, non-randomized

Settings and conduct

People referred to physiotherapy clinics are invited to participate in this study if they wish. After checking the inclusion and exclusion criteria and completing the written consent form to participate in the research, the patients will enter the study. The treatment procedure and evaluation of people will be done in the physical medicine and rehabilitation clinic of Firouzgar Hospital and the National Brain Mapping Laboratory. After completing the questionnaire containing demographic information, people are subjected to initial evaluation, which includes: functional balance tests (Timed up and go test and Four square steps) and checks neuromodulation with TMS-EMG parameters, and assessment of the intensity of spasticity with the Modified Modified Ashworth scale, also the active and passive range of motion of dorsiflexion of the ankle. After three weeks of intervention (one session of dry needling of the plantar flexor muscles each week, including the internal and external heads of gastrocnemius muscles and the soleus muscle), the subjects are re-evaluated and all the tests are re-evaluated will be In order to check the durability of the effects and follow up two weeks after the end of the intervention, re-evaluations will be done.

Participants/Inclusion and exclusion criteria

People with Relapsing and Relapsing MS and stroke

Intervention groups

After the first evaluations, all subjects will receive dry

needling for the gastrocnemius (medial and lateral head) and soleus muscles using a 0.30 x 50 mm filiform needle for one minute for each muscle.

Main outcome variables

Neuromodulation- Spasticity-Balance

General information

Reason for update

Acronym

به اختصار می شود DN, Multiple sclerosis به MS اختصار می شود

IRCT registration information

IRCT registration number: **IRCT20230206057343N1**

Registration date: **2023-02-09, 1401/11/20**

Registration timing: **prospective**

Last update: **2023-02-09, 1401/11/20**

Update count: **0**

Registration date

2023-02-09, 1401/11/20

Registrant information

Name

Haniyeh Choobsaz

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

2023-03-01, 1401/12/10

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effects of Dry Needling of Gastrocnemius - Soleus muscles on Neuromodulation, Spasticity, and Balance in patients with MS (relapsing-remitting) and stroke

Public title

Comparing the effects of dry needling of ankle plantar flexor muscles on neuromodulation, spasticity, and balance in people with MS and stroke.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Remitting and relapsing Multiple sclerosis disease Having a stroke EDSS score less than 4 in the group of MS patients Follow instructions Spasticity of plantarflexors is equal to or greater than 1 using (MMAS scale) No diabetes Absence of any history of treatment with nerve blockers, or treatment with botulinum toxin A 6 months before entering the study. No history of attacks in MS patients in the last 8 weeks Absence of limitation of passive range of motion of more than 10 percent in ankle dorsiflexion compared to the less involved leg (absence of contracture). Absence of other neurological disorder

Exclusion criteria:

Fear of dry needling Recurrent stroke during the patient evaluation and intervention program Occurrence of a new attack in a patient with MS Contraindications to the use of TMS

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **20****Randomization (investigator's opinion)**

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

The study is a prospective clinical trial, where the subjects are in two different disease groups (multiple

sclerosis and stroke), which are non-randomly placed in two groups, and the subjects receive the same intervention.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee on Research in Nursing and Midwifery Faculty and Faculty of Rehabilitation, Tehran

Street address

Tehran, District 12, Enghelab St. Pich-e-Shemiran

City

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Province

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Postal code

1148956111

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.TUMS.FNM.REC.1401.167

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

Multiple Sclerosis (Relapsing Relapsing)

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

2**Description of health condition studied**

Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

Neuromodulation

Timepoint

Before the intervention, After 3 sessions of intervention, and 2 weeks after for follow up

Method of measurement

With Trans-cranial magnetic stimulation parameters, Including motor evoked potential (MEP) amplitude at rest

and muscle motor threshold at rest (RMT) and motor evoked potential amplitude ratio in intracortical inhibition protocol (SICI) and motor evoked potential amplitude ratio in intracortical facilitation protocol (ICF).

2

Description

Spasticity

Timepoint

Before the intervention, after 3 sessions of intervention sessions, and two weeks after the last intervention session for follow-up

Method of measurement

Modified Modified Ashworth Scale

Secondary outcomes

1

Description

Functional Balance

Timepoint

Before the intervention, after 3 sessions of intervention sessions, and two weeks after the last intervention session for follow-up

Method of measurement

Timed up and go test and Four Square Step test

2

Description

Active and Passive ankle dorsiflexion ROM

Timepoint

Before the intervention, after 3 sessions of intervention sessions, and two weeks after the last intervention session for follow-up

Method of measurement

The evaluation will be done using a goniometry

Intervention groups

1

Description

Intervention group: Dry needling will be done on the internal and external head of the gastrocnemius muscle, and the soleus muscle (in the area of the motor point) by using a 0.30 x 50 mm foliform needle for one minute. For each muscle, dry needling by the fast in fast out method and in a cone shape will be done. Dry needling will be done for three weeks and one session every week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Bijan Forough

Street address

Firoozgar Hospital, Beh Afarin St., Karim Khan Zand Blvd., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fatuhi

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Keshavarz Blvd., corner of Qods St., Central Organization of Tehran University of Medical Sciences, 6th floor

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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

Tehran 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

Tehran University of Medical Sciences
Full name of responsible person
Nastaran Ghotbi
Position
Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Yes - There is 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

If needed by the researchers and their request, the raw data of the research and its analysis will be provided to researchers

When the data will become available and for how long

After the publication of the articles resulting from the research

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

The data is only available to other researchers to study and review treatment results Placed

From where data/document is obtainable

By sending an email to the corresponding author

What processes are involved for a request to access data/document

Send an email to the responsible author and request the document

Comments