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 Remitting 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

Dry needling به اختصار می شود DN و, Multiple sclerosis به اختصار می شود MS

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
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Name of organization / entity
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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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target 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
Tehran
Province
Tehran
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 (Remitting 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 ofTehran University of Medical Sciences, 6th floor
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Postal code
1417653761
Phone
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vcr@tums.ac.ir
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

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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Position
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Latest degree
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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
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