Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effects of dry needling on spastic gastronemius muscle in patients with multiple sclerosis

Protocol summary

Study aim
Determining the Clinical, Biomechanical and Functional Effects of Dry Needle on Spastic Gastrocnemius Muscle in Patients with Multiple Sclerosis

Design
Controlled clinical trial, parallel group trial, double blinded examiner and participant, randomised

Settings and conduct
The study is conducted at the Physical Therapy Clinic of Sina hospital. Participants will pass two test categories (standing and sitting). After the end of the evaluation, the patients in the waiting list are waiting to be reassessed and in the DN treatment group, when the patient are in prone position, DN will be done for gastrocnemius muscle. All evaluations will be repeated for the following two weeks as follow-ups.

Participants/Inclusion and exclusion criteria
People with MS who have spasticity in the lower limbs. arrival conditions: Definitive diagnosis of MS (relapsing-remitting type) Lake of other neurological diseases Ability to walk with or without auxiliary equipment EDSS with a score of 3 to 7 Severity of spasticity of plantar flexors is equal to or greater than 1(using MMAS) Lack of passive ankle limitation is more than 10% No acute attack in the last month Non-arrival conditions: Unwillingness to continue cooperation of patient for any reason Occurrence of a new attack during the course of participating research Use of anti-spasticity drugs during the research period

Intervention groups
After the end of frist evaluation, the patients in the waiting list are waiting to be reassessed and in the DN treatment group, when the patient are in prone position, the con shaped dry needling (0/22*30) will be done for one minute for each muscle on the medial and latral heads of the gastrocnemius muscle.

Main outcome variables
MMAS measurements, active and passive motion range, and the passive torque of the ankle plantar flexor, pressure in different points of foot and dynamic mobility test for lower limb.

General information

Reason for update
Due to the prevalence of coronavirus, more time is needed to gather information.

Acronym
Dry needling به اختصار می شود DN ، Multiple sclerosis به اختصار می شود MS

IRCT registration information
IRCT registration number: **IRCT20190617043918N1**
Registration date: **2019-07-03, 1398/04/12**
Registration timing: **prospective**

Last update: **2020-11-09, 1399/08/19**
Update count: **1**

Registration date
2019-07-03, 1398/04/12

Registrant information

Name
Omid Motamedzadeh sabeti

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2286 7320

Email address
motamedzadeh-o@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-22, 1398/04/31

Expected recruitment end date
2021-12-21, 1400/09/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of dry needling on spastic gastronemius muscle in patients with multiple sclerosis

Public title
Study of the clinical, biomechanical, and functional effects of dry needling on spastic gastronemius muscle in patients with multiple sclerosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Definitive diagnosis of MS (relapsing-remitting type) Lake of other neurological diseases Ability to walk with or without auxiliary equipment Ability to understand commands EDSS with a score of 3 to 7 Severity of spasticity of plantar flexors is equal to or greater than 1(using MMAS) Lack of passive ankle limitation is more than 10% Lake of Botox injection since three months ago Absence of any kind of confrontation for DN No acute attack in the last month
Exclusion criteria:
Unwillingness to continue cooperation of patient for any reason Occurrence of a new attack during the course of participating research Use of anti-spasticity drugs during the research period
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization Patients are randomly divided into treatment and control groups. In order to randomly distribute patients, packets that are packed in equal quantities for both groups will be prepared and contain the terms "treatment" and "control" that will be selected by the secretary and will be entered into the treatment or control group accordingly.
Blinding (investigator's opinion)
Double blinded
Blinding description
This is a double-blind clinical study, in which an experienced physiotherapist will be doing intervention and another physiotherapist will be evaluating. As a result, the evaluator does not know which group the patient belongs to. On the other hand, patients are unaware of whether they are in the intervention group or on the waiting list.
Placebo
Not used
Assignment
Parallel
Other design features

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
School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran
City
tehran
Province
Tehran
Postal code
11489-65111
Approval date
2019-05-19, 1398/02/29
Ethics committee reference number
IR.TUMS.FNM.REC.1398.022

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
spasticity of plantar flexors muscles measured its intensity based on the MMAS scale from zero to four.
Timepoint
measurements will be done before intervention, immediately after it and one week later.
Method of measurement
spasticity is the resistance level that the therapist felt during dorsiflexion of the patient's ankle and measured its intensity based on the MMAS scale from zero to four.

2

Description
Passive torque of plantar flexor muscles , The maximum force obtained in terms of Newton’s is multiplied to distance (m) between the head of the third metatarsal to the ankle joint axis and the maximum torque is obtained in terms of Nm.

Timepoint
measurements will be done before intervention, immediately after it and one week later.

Method of measurement
An ankle stiffness is evaluated using a manual micro-muscle tester. The center of the sensitive dynamometer pad is locating in the center of the metatarsal arch in the third metatarsal head, and the passive resistance force of the plantar flexors against the ankle dorsiflexion is recorded by dynamometer in the knee extension position. In this way, like the clinical method of measuring spasticity by counting 1001, the ankle joint will be quickly turned from its rest position to the maximum dorsiflexion.The maximum force obtained in terms of Newton’s is multiplied to distance (m) between the head of the third metatarsal to the ankle joint axis and the maximum torque is obtained in terms of Nm.

3

Description
Maximum foot pressure, for study of foot pressure in static, the maximum pressure and foot force variables are examined by the foot scan.

Timepoint
measurements will be done before intervention, immediately after it and one week later.

Method of measurement
we want the patient to stand straight and look at the point on the facing wall and count from 100 in reverse, then the at time interval when the patient is counting and concentrating, operator scans the participant's foot.

4

Description
In this research, dynamic mobilities test is determined by measuring the time taken to run the Time up and go (TUG) test by stopwatch.

Timepoint
measurements will be done before intervention, immediately after it and one week later.

Method of measurement
the examiner asks the patient to sit comfortably on an armchair with his legs touching the ground, and by the therapist order, "go" rose up from the chair, and passing a 3-meter distance on the ground, then round and return to the same seat and sits down. Eventually, time is recorded using a timer.

Secondary outcomes

1

Description
dorsiflexion range of motion

Timepoint
measurements will be done before intervention, immediately after it and one week later

Method of measurement
To do this, an ankle goniometr is used. To measure active range of motion, we ask the patient to perform ankle dorsiflexion in a straight-knee position. To measure the passive range, keep the tibia and the fibula with one hand and hold the heel together with the flat plate of the goniometer with another hand and pull it slowly down to achieve the maximum dorsiflexion.

Intervention groups

1

Description
Intervention group: in the interventional group, DN , when the patient are in prone position, the con shaped dry needling will be done for one minute for medial and latral heads of the gastrocnemius muscle.In the prone position, a pillow is placed under the spastic foot of the patient, a line will be drawn from the middle of the linear heel to the populiteal fossa’s middle point, dividing the line into three parts, and then move 2 cm in the middle of the proximal segment towards the lateral side of shin, and needle is penetrated. The procedure for dry needing of the medial head of the gastrocnemius muscle is like that of latral head, except that it will be penetrated moving of 1/3 of distal part of proximal segment towards shin.

Category
Rehabilitation

2

Description
Control group: In control group, after first evaluations, the patients will be wait to be reassessed (without any intervention).

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Sina Hospital

Full name of responsible person
Sara Hamtaie Gashti

Street address
Sina Hospital, Emam Khomeini Ave

City
Tehran

Province
Tehran

Postal code
١١٣٦٧٤٦٩١١

Phone

+98 21 6634 8500

Email

hosp_sina@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Seyed Ahmadreza Khatoonabadi

Street address

School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran

City

Tehran

Province

Tehran

Postal code

11489-65111

Phone

+98 21 7762 8205

Email

khatoonabadi@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

70

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

Omid Motamedzadeh Sabeti

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran

City

Tehran

Province

Tehran

Postal code

11489-65111

Phone

+98 21 2286 7320

Email

motamedzadeh-o@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Omid Motamedzadeh Sabeti

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Province

Tehran

Postal code

11489-65111

Phone

+98 21 2286 7320

Email

motamedzadeh-o@razi.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Omid Motamedzadeh Sabeti

Position

PhD Student

Latest degree

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Other areas of specialty/work

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Tehran

Province

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Postal code

11489-65111

Phone

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Email
motamedzadeh-o@razi.tums.ac.ir

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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The whole data can be shared after unidentifiable people.
When the data will become available and for how long
Six months after the publication of each group results , release the data is possible.
To whom data/document is available
Data access is free to the public.
Under which criteria data/document could be used
The use of data in order to achive the study mechanism is free.
From where data/document is obtainable
To receive the data, please contact Mr. Omid Motamedzadeh Sabeti with the following emails and address. motamedzadeh-o@ razi.tums.ac.ir motamed.omid@yahoo.com School of Rehabilitation,Tehran University of Medical Sciences, Enghelab Ave., Piche-e-shemiran
What processes are involved for a request to access data/document
The applicant submits an application to Mr. Omid Motamedzadeh by sending an email and after receiving the identity information, the data will be sent to him.
Comments