

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of the effects of dry needling on spastic gastrocnemius 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) Lack 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 first 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 lateral 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)

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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
gastrocnemius muscle in patients with multiple sclerosis

Public title

Study of the clinical, biomechanical, and functional
effects of dry needling on spastic gastrocnemius muscle in
patients with multiple sclerosis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Definitive diagnosis of MS (relapsing-remitting type) Lack
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% Lack 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

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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 goniometer 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 lateral 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 popliteal 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 needling of the medial head of the gastrocnemius muscle is like that of lateral 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr. Seyed Ahmadrza Khatoonabadi

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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

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

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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

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 achieve 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