Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Effects of dry needling plus static stretching on plantar flexors spasticity, alpha motor neuron excitability, and balance in patients with chronic stroke

Protocol summary

Study aim

If the use of dry needling plus static stretching causes a greater reduction in the spasticity of ankle plantarflexor muscles, this method can be suggested for use in clinics to achieve more effective physiotherapy intervention in chronic stroke patients.

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 26 patients.Randomization by cards or envelopes Shuffling

Settings and conduct

This study is conducted in the clinic of the rehabilitation faculty of Tehran University. In this study, the evaluation is done once before the treatment, once at the end of the treatment, and once a week after the treatment. In the intervention group, after dry needling for 60 seconds, 20 minutes of plantar flexor muscle stretching is applied using the designed orthosis. In the control group, in addition to Sham dry needling in the form of a 10-gram monofilament, static stretching is performed for 20 minutes using an orthosis. Static stretching is performed for 5 sessions with a frequency of once a day and 5 days a week, and dry needling is performed for 3 sessions with a frequency of once a day and 3 days a week.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1) Men and women with chronic stroke 2) Age between 40 to 65 years Exclusion Criteria: 1) Passive ROM limitation of more than 10% in ankle dorsiflexion compared to the less involved leg. 2) Non-cooperation in carrying out treatment protocols

Intervention groups

In the intervention group, dry needling plus static stretching will be applied to the plantar flexor muscles. Sham dry needling and static stretching will be applied in the control group.

Main outcome variables

Modified modified Ashworth scale (MMAS) • Passive and active range of motion • H reflex latency and the values of the Hmax/Mmax ratio • Timed up and go test • Euro Qol questionnaire (EQ-5D-5L)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058844N1**
Registration date: **2023-08-07, 1402/05/16**
Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**
Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Mahdi Esmaeeli

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of dry needling plus static stretching on plantar flexors spasticity, alpha motor neuron excitability, and balance in patients with chronic stroke

Public title
Effects of dry needling plus static stretching on plantar flexors spasticity, alpha motor neuron excitability, and balance in patients with chronic stroke
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women with chronic stroke At least 6 months after stroke onset MMAS≥1 for the ankle plantar flexor muscle group Ability to walk 10 meters independently with or without an assistive device Having no pain in lower limb No history of botox injection in the plantar flexor muscles in the last 3 months No contraindication for dry needling No history of other neuromuscular system disorders Ability to understand and follow the instructions Age between 40 to 65 years
Exclusion criteria:
Passive ROM limitation of more than 10% in ankle dorsiflexion compared to the less involved leg. Non-cooperation in carrying out treatment protocols Absence of the person in two consecutive treatment sessions Inability to complete the pre and post assessments
Age
From **40 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **26**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the participants were divided into two groups by a simple random method with the help of shuffling the closed envelopes (Cards or Envelopes Shuffling) which were prepared according to their number and one of the names of the intervention or control was written on it. All patients have the same chance of being placed in any of the two groups. This study is a double-blind study. In this study, due to the use of sham dry needling, patients in the control group will be blinded of their placement in the intervention and control groups. Also, the assessor is blinded of the control and intervention groups and only knows them as groups A and B. Only the interventionist is aware of the research events.

Blinding (investigator's opinion)
Double blinded
Blinding description
The assessor is the researcher and during the evaluations, he is not aware of the grouping of the patients and only knows them into two groups A and B. The use of dry needling as a sham in the control group causes the patient to be blinded to being in the control or intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o
Street address
3rd Floor, Rashidi Alley, Meghdad St, Pirouzi Ave
City
Tehran
Province
Tehran
Postal code
1766717194
Approval date
2023-07-18, 1402/04/27
Ethics committee reference number
IR.TUMS.FNM.REC.1402.097

Health conditions studied

1

Description of health condition studied
Chronic stroke patients
ICD-10 code
G81.1
ICD-10 code description
Spastic hemiplegia

Primary outcomes

1

Description
Hmax/Mmax
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Using an electromyography device

2

Description
H reflex latency
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Using an electromyography device

3

Description
Modified modified Ashworth scale (MMAS)
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Score between 0-4 by assessor (MMAS)

4

Description
Ankle active range of motion
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Goniometer

5

Description
Ankle passive range of motion
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Goniometer

6

Description
Timed up and go test
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
Time measured by a chronometer

7

Description
quality of life
Timepoint
Before the intervention, after the intervention, one week after the intervention
Method of measurement
European quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention:In the intervention group, in each treatment session, after dry needling for 60 seconds, 20 minutes of stretching (29) of the plantar flexor muscles are applied using the designed orthosis. The reason for the superiority of dry needling over stretching is the effects of dry needling on the reduction of acetylcholine available to the muscle, which can make stretching more effective and increase the range of stretching.A) Dry needlingFor dry needling, a sterile disposable needle (size 0.30mm x 0.50mm and brand SMC, Seoul, Korea) is used. The patient is asked to lie prone on the bed and hang the ankle over the edge of the bed, and the Fast in Fast Out technique is used on the medial and lateral head of the gastrocnemius muscle for 60 seconds (25). According to Figure 2, the exact location of the dry needle is determined by drawing a line to connect the center of the popliteal cavity to the heel, and two centimeters inside and outside the proximal third of this line, the needle enters the inner head and It becomes external to the gastrocnemius muscle (25). The depth of the needle is adjusted depending on the opinion of the therapist and the depth of the subcutaneous tissue of the patient. The number of treatment sessions for dry needling is done with a frequency of once a day, three times a week on alternate days, and for a week.b) Static tensionTo apply traction, an orthosis designed by a technical orthopedic expert is used. The upper plate of this orthosis is for placing the leg and the lower plate is for placing the sole of the foot. These two upper and lower plates are connected to each other by adjustable screws for range of motion. This orthosis can be adjusted in different ranges of the ankle joint (Figure No. 3). In order to perform stretching, the patient sleeps supine in a completely calm and relaxed position with straight knees. The patient is requested not to make any contraction in the ankle and the orthosis is adjusted in the maximum range of dorsiflexion in the ankle (31). The number of treatment sessions for stretching is performed with a frequency of once a day, five times a week, and for one week (53).
Category
Rehabilitation

2

Description
Control group: In the control group, in each treatment session, in addition to Sham dry needling in the form of 10 g monofilament for three sessions, static stretching for 20 minutes and for five sessions using an orthosis (36) is performed. The use of dry needling as a sham causes the patient to be blinded to being in the control or intervention group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Clinic of school rehabilitation, Tehran universitiy of medical science

Full name of responsible person
School of rehabilitation, Tehran universitiy of medical science

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
Mahdi Esmaeeli

Position
MSc student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
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
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