# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 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)

**Phone**

+98 21 3317 0630

**Email address**

mesmaeeli@razi.tums.ac.ir

**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

**Street address**
School of rehabilitaion, Tehran universiti of medical science

**City**
Tehran

**Province**
Tehran

**Postal code**
6511111489

**Phone**
+98 21 7753 3939

**Email**
rehabilitation@tums.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Tehran University of Medical Sciences

**Full name of responsible person**
Dr. Akbar Fotouhi

**Street address**
Enghelab Ave,Tehran University of Medical Sciences

**City**
Tehran

**Province**
Tehran

**Postal code**
6511111489

**Phone**
+98 21 8163 3619

**Email**
tumspr@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**
Mahdi Esmaeeli

**Position**
MSc student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Physiotherapy

**Street address**
3rd Floor, No 10, Rashidi Alley, Meghdad St, Pirouzi Ave, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1766717194

**Phone**
+98 21 3317 0630

**Fax**

**Email**
mesmaeeli@razi.tums.ac.ir

## Person responsible for scientific 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

**Street address**
3rd Floor, No 10, Rashidi Alley, Meghdad St, Pirouzi Ave, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1766717194

**Phone**
+98 21 3317 0630

**Fax**

**Email**
mesmaeeli@razi.tums.ac.ir

## Person responsible for updating data

mesmaeeli@razi.tums.ac.ir

**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

**Street address**
3rd Floor, No 10, Rashidi Alley, Meghdad St, Pirouzi Ave, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1766717194

**Phone**
+98 21 3317 0630

**Fax**

**Email**

## 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