

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of transcutaneous electrical nerve stimulation with and without dry needling on wrist flexors spasticity, motor function and motor neuron excitability in patients with chronic stroke

Protocol summary

Study aim

Comparison of the effect of transcutaneous electrical nerve stimulation with and without dry needling on wrist flexor spasticity, motor function, and motor neuron excitability in patients with chronic stroke

Design

A randomized, controlled, double-blind, parallel-group clinical trial on at least 28 patients, randomized using a block randomization method using web-based randomization (www.sealedenvelope.com).

Settings and conduct

Patients will be included in the study with convenient sampling method. Patients with chronic stroke resulting in hemiplegia who are referred to Tehran University Brain Injury Clinics and Treatment Centers will be selected based on the inclusion and exclusion criteria. After completing the informed consent form and random assignment, the patients' background information and then clinical assessments will be recorded (by an assessor unaware of the patient grouping).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Hemiplegia due to ischemic stroke 2. At least 6 months after the stroke 3. Spasticity severity of the wrist flexor muscles of the affected side according to the MMAS scale of at least 1 4. Age 40 to 70 years 5. Ability to follow instructions Exclusion criteria: 1. Taking any medication that is effective in reducing spasticity.

Intervention groups

The groups include: 1- Intervention group (transcutaneous electrical nerve stimulation and dry needling) 2- Control group (transcutaneous electrical nerve stimulation). Interventions for both groups are performed by an experienced physiotherapist for 1 week and 3 sessions per week.

Main outcome variables

Wrist muscle spasticity severity; wrist active and passive range of motion; motor function; alpha motor neuron

excitability; H reflex latency.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260128068683N1**

Registration date: **2026-05-18, 1405/02/28**

Registration timing: **registered_while_recruiting**

Last update: **2026-05-18, 1405/02/28**

Update count: **0**

Registration date

2026-05-18, 1405/02/28

Registrant information

Name

Mahla Rakhshani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 541 5622

Email address

m-rakhshani@razi.tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-02-19, 1404/11/30

Expected recruitment end date

2027-02-09, 1405/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of transcutaneous electrical nerve stimulation with and without dry needling on wrist flexors spasticity, motor function and motor neuron excitability in patients with chronic stroke

Public title

Comparison of the effect of transcutaneous electrical nerve stimulation with and without dry needling on wrist flexors stiffness, motor function and motor neuron excitability in patients with chronic stroke

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hemiplegia due to ischemic stroke At least 6 months have passed since the stroke Spasticity severity of the wrist flexor muscles of the affected side according to the MMAS scale of at least 1 Age 40 to 70 years Ability to follow instructions

Exclusion criteria:

Taking any medication that is effective in reducing spasticity.

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to groups using a permuted block randomization method using web-based randomization (www.sealedenvelope.com). Random allocation concealment method: Use of sequentially numbered, sealed, opaque envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will not know which treatment group they are assigned to (both groups will receive the same treatment except for dry needling, which the control group will receive as a sham). The outcome assessor and data analyst will also be unaware of the treatment and group each patient received.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Faculty of Rehabilitation of Tehran University of Medical Sciences, Corner of Safi Alishah St., Enghelab St.

City

Tehran

Province

Tehran

Postal code

1148965111

Approval date

2025-06-14, 1404/03/24

Ethics committee reference number

IR.TUMS.FNM.REC.1404.078

Health conditions studied**1****Description of health condition studied**

Patients with chronic stroke

ICD-10 code

I67.9

ICD-10 code description

Cerebrovascular disease, unspecified

Primary outcomes**1****Description**

Spasticity severity

Timepoint

Before the start of the intervention, 7 and 28 days after the start of the intervention

Method of measurement

Modified Modified Ashworth Scale

2**Description**

Active range of motion of the wrist

Timepoint

Before the start of the intervention, 7 and 28 days after the start of the intervention

Method of measurement

Goniometer

3

Description

Active range of motion of the wrist

Timepoint

Before the start of the intervention, 7 and 28 days after the start of the intervention

Method of measurement

Goniometer

4

Description

Motor function

Timepoint

Before the start of the intervention, 7 and 28 days after the start of the intervention

Method of measurement

Box and Block Test

5

Description

Motor neuron excitability

Timepoint

Before the start of the intervention, 7 and 28 days after the start of the intervention

Method of measurement

Electromyography device

6

Description

H reflex latency

Timepoint

Before the start of the intervention, 7 and 28 days after the start of the intervention

Method of measurement

Electromyography device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Transcutaneous electrical nerve stimulation with a frequency of 100 Hz and a pulse duration of 200 microseconds for 30 minutes while the patient is in the supine position and two surface electrodes with dimensions of 4 and 6 cm are placed on the forearm muscle bundle with a distance of 2.5 cm. The current intensity will be based on the patient's sensation and will be twice the sensory threshold. After receiving electrical stimulation, dry needling of the wrist flexor muscles is received while the patient lies in a supine position and dry needling is used on the flexor carpi radialis and flexor carpi ulnaris muscle bundle. For both muscles, the desired area is first disinfected with alcohol and then Fast-in and Fast-out are

performed for one minute for each muscle according to the method of Ansari et al. After that, patients perform routine exercise therapy (standard exercises based on neurodevelopmental treatment including functional mobility exercises, active range of motion, and stretching exercises).

Category

Rehabilitation

2

Description

Control group: Transcutaneous electrical nerve stimulation at a frequency of 100 Hz and a pulse duration of 200 μ s for 30 minutes while the patient is in the supine position and two surface electrodes measuring 4 and 6 cm are placed on the forearm muscle bundle with a distance of 2.5 cm from each other. The current intensity will be based on the patient's sensation and will be twice the sensory threshold. After receiving electrical stimulation, the dry needle placebo will be applied to the wrist flexor muscles while the patient is lying in a supine position and the dry needle placebo will be applied to the same points as the intervention group via dry needle-like microfilaments on the flexor carpi radialis and flexor carpi ulnaris muscle bundle. For both muscles, the desired area is first disinfected with alcohol and then, according to the method of Ansari et al., Fast-in and Fast-out are performed for one minute for each muscle. After that, patients perform routine therapeutic exercises (standard exercises based on neurodevelopmental treatment including functional mobility exercises, active range of motion, and stretching exercises).

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shafayahyaeian hospital

Full name of responsible person

Mahla Rakhshani

Street address

Mojahedin Eslam St., Baharestan square.

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 3354 2001

Email

shafa.iums@gmail.com

Web page address

<https://en-ipdshafa.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ramin Kordi

Street address

Qods Ave, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 3939

Fax**Email**

research@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

Mahla Rakhshani

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Corner of Safi Alishah St., Shemiran Intersection.,
Enghelab St.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 3939

Email

rakhshanim500@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Nouredin Nakhostin Ansari

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

corner of Safi Alishah St., Enghelab St.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 3939

Fax

+98 21 7753 4133

Email

nakhostin@sina.tums.ac.ir

Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahla Rakhshani

Position

PhD Candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Corner of Safi Alishah St., Enghelab St.

City

Tehran

Province

Tehran

Postal code

1148965111

Phone

+98 21 7753 3939

Email

m-rakhshani@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

If published, the overall data (data related to all outcomes before and after the intervention) and its results will be published without disclosing the personal information of the participants. The results from the

primary and secondary assessments will be presented as averages in the table.

When the data will become available and for how long

Access period starts 6 months after results are published.

To whom data/document is available

It will only be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

They can use the results obtained for review studies.

Access is possible if academic and scientific responsibility is established.

From where data/document is obtainable

Applicants can send their application to the researcher's email address: rakhshanim500@gmail.com

What processes are involved for a request to access data/document

The applicant can access the information by providing valid proof of academic affiliation to the university by sending this proof to the researcher's email.

Comments