Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Due to website and internet-related issues during the months of 2025 and 2026, the clinical trial approval is expected to be issued after the anticipated start of patient recruitment; therefore, the expected start date for patient recruitment has been changed to 20 May 2026 .

Acronym

IRCT registration information

IRCT registration number: **IRCT20260128068683N1**
Registration date: **2026-05-18, 1405/02/28**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-25, 1405/08/03**
Update count: **1**

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

2025-05-20, 1404/02/30

Expected recruitment end date
2028-02-09, 1406/11/20
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 µs 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 Noureddin 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