Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of two methods transcutaneous electrical nerve stimulation and progressive muscle relaxation on fatigue in stroke patients

Protocol summary

Study aim
Comparison of the effects of transcutaneous electrical nerve stimulation and progressive muscle relaxation on fatigue in patients with stroke

Design
The present study is a three-arm, randomized clinical trial with a control group, being conducted at Ghaem Hospital in Mashhad. Patient allocation will be performed using random blocks of sizes 3 and 6, via the Sealed Envelope system.

Settings and conduct
The present study is being conducted in the Neurology 1, Neurology 3, and SCU wards of Ghaem Hospital in Mashhad. Patients are randomly assigned to three groups: TENS, Progressive Muscle Relaxation (PMR), and a control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed ischemic stroke, full consciousness, mild functional impairment, age 30–75 years, hospitalization between days 3 and 7, stable vital signs, informed consent, ability to communicate, sufficient literacy, and access to a mobile phone. Exclusion Criteria:Severe and unstable physical or psychiatric disorders, use of antidepressant or sedative medications, presence of implanted electronic devices, skin lesions at the electrode placement sites, history of epilepsy, use of similar complementary therapies, and allergy to electrode adhesives or nickel.

Intervention groups
In the TENS group, bilateral stimulation of the common peroneal nerve is performed using a Burgess device for 30 to 45 minutes daily over a period of 5 days. In the PMR group, Jacobson’s progressive muscle relaxation—supported by instruction and an educational video—is administered for the same duration. The control group receives routine hospital care.

Main outcome variables
Fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20261023071529N1**
Registration date: **2026-11-20, 1405/08/29**
Registration timing: **prospective**

Last update: **2026-11-20, 1405/08/29**
Update count: **0**

Registration date
2026-11-20, 1405/08/29

Registrant information

Name
Matina Rajaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 5725 3229

Email address
rajaeim4042@mums.ac.ir

Recruitment status
Not yet recruiting

Funding source

Expected recruitment start date
2026-12-06, 1405/09/15

Expected recruitment end date
2027-03-06, 1405/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of two methods transcutaneous electrical nerve stimulation and progressive muscle relaxation on fatigue in stroke patients

Public title
Comparison of the effects of two methods transcutaneous electrical nerve stimulation and progressive muscle relaxation on fatigue in stroke patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of ischemic stroke by a specialist physician(CT or MRI) Full level of consciousness (GCS=15) MRS score less than or equal to 2 Being between the third and seventh day of hospitalization Ages 30 to 75 Stability of vital signs Informed consent for participation in the study Sufficient visual, auditory, cognitive ability to respond questions. Absence of paralysis of the limbs Access to a mobile phone for online training and questionnaires Ability to read and write Absence of severe and unstable physical or psychiatric illnesses Absence of implanted electronic devices Absence of skin lesions at the electrode placement sites Not taking antidepressants or sedatives Lack of sensitivity to adhesive or nickel Absence of pregnancy Absence of epilepsy

Exclusion criteria:
Suffering from severe and unstable physical or psychiatric illnesses Use of antidepressant or sedative medications Presence of implanted electronic devices Skin lesions at the electrode placement sites History of epilepsy Use of similar complementary treatments Allergy to electrode adhesives or nickel

Age
From **30 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **117**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be assigned to three groups TENS, Progressive Muscle Relaxation (PMR), and a control group, using a block randomization method with block sizes of three and six, facilitated by the online system "Sealed Envelope." Following the generation of the randomization sequence, assignments will be designated by codes A, B, and C, and placed into opaque, sealed, and numbered envelopes. As each eligible patient enters the study, the corresponding envelope (in numerical order) will be opened to reveal the assigned group. This process will continue until the required sample size is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description

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 & Midwifery - Mashhad university Of Medical Sciences

Street address
School of Nursing and Midwifery, Shahid Dr.Kharazmi Educational Complex, Medical Sciences Campus, Eastern Entrance of Ferdowsi University, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2026-10-06, 1405/07/14

Ethics committee reference number
IR.MUMS.NURSE.REC.1405.086

Health conditions studied

1

Description of health condition studied
Stroke

ICD-10 code
I60

ICD-10 code description
Nontraumatic subarachnoid hemorrhage

2

Description of health condition studied
Stroke

ICD-10 code
I61

ICD-10 code description
Nontraumatic intracerebral hemorrhage

3

Description of health condition studied

Stroke

ICD-10 code

I62

ICD-10 code description

Other and unspecified nontraumatic intracranial hemorrhage

4

Description of health condition studied

Stroke

ICD-10 code

I63

ICD-10 code description

Cerebral infarction

Primary outcomes

1

Description

Fatigue Score

Timepoint

Measurement of fatigue at the beginning (before the intervention) and at the end of the intervention (after the final intervention session)

Method of measurement

Multidimensional Fatigue Inventory (MFI)

Secondary outcomes

1

Description

Degree of disability or dependence in activities of daily living among individuals who have suffered a stroke

Timepoint

Measurement at the beginning (pre-intervention) and at the end of the intervention (after the final intervention session)

Method of measurement

(Modified Rankin Scale - MRS)

Intervention groups

1

Description

Intervention group: The TENS intervention will be administered by the researcher using a Berjis ST90 device. It will involve bilateral stimulation of the common peroneal nerve at a frequency of 100 Hz and a pulse width of 200 microseconds. The intensity will be set to a tolerable sensory level—below the motor threshold—and the intervention will be applied daily for 30 to 45 minutes over 5 consecutive days.

Category

Treatment - Devices

2

Description

Intervention group: The progressive muscle relaxation intervention, based on the Jacobson method, will be conducted daily for 30 to 45 minutes over 5 consecutive days, following instruction by the researcher and the use of an educational video. The exercises will be performed in a lying position, proceeding from head to toe; this involves contracting the muscles for 5 to 10 seconds, followed by a 5-second release, all under the supervision and guidance of the researcher.

Category

Rehabilitation

3

Description

Control group:This group will not receive a placebo and will instead receive only the standard care provided in the ward, in accordance with hospital protocol. Such care encompasses routine nursing interventions, pharmacological treatment as prescribed by the attending physician, physiotherapy (if ordered), and other standard care typically provided to patients hospitalized during the acute phase of a stroke. No interventions such as Transcutaneous Electrical Nerve Stimulation (TENS) or Progressive Muscle Relaxation (PMR) will be administered to this group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Matina Rajaee

Street address

Ahmadabad Boulevard, Mashhad, Razavi Khorasan Province, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9176699199

Phone

+98 51 3840 0001

Email

rajaeim4042@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

tayebe pourghaznein

Street address

Shahid Dr.Kharazmi Educational Complex, University Campus, Eastern Entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 915 513 5805

Email
pourghazneint@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Matina Rajaee

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Dr.Kharazmi Educational Complex, University Campus, Eastern Entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 902 960 6617

Email
rajaeim4042@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
tayebe pourghaznein

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

Street address
Shahid Dr.Kharazmi Educational Complex, University Campus, Eastern Entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
05131428000- 8728

Email
pourghazneint@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Matina Rajaee

Position
Master's student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Dr. Kharazmi Educational Complex, University Campus, Eastern Entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Phone
+98 902 960 6617

Email
rajaeim4042@mums.ac.ir

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