Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the Effects of Extracorporeal Shockwave Therapy and Pulsed Ultrasound on Spasticity neurophysiological and Functional outcomes in Patients with Stroke

Protocol summary

Study aim
trial aims to compare the effectiveness of ESWT and pulsed US in reducing plantar flexor spasticity in individuals with stroke

Design
Single-Blind Randomized Controlled Trial

Settings and conduct
patients referred to the Neurophysiotherapy Clinic at the School of Rehabilitation, as well as those attending neurological and neurorehabilitation clinics within TUMS, will be recruited for this study.will be conducted using a convenience sampling method

Participants/Inclusion and exclusion criteria
. inclusiion 1.First-ever stroke. 2. Stroke duration of at least 6 months and less than 48 months 3. Age 40-70 years 4. Ankle plantar flexor MMAS score ≥1 5. Be able to walk independently 6. Stable vital signs. 7. constant drug protocol doses - Exclusion criteria 1. Sensation deficits in the foot area 2. Currently being treated for spasticity 3. Wound or infection in the affected lower limb (4. Ultrasound and shockwave contraindications. 5. Radial extracorporeal shock wave therapy (rESWT) contraindications (pregnancy, On major 6. vessels and nerves, Pacemaker or other implanted devices, Open wounds, Joint 7. Fixed ankle joint contracture 8. History of Botox . alcohol or phenol block treatments within previous 6 months ago 9. Severe pain with rSWET

Intervention groups
1-Shock Wave Group (rESWT) 2-Ultrasound Group (Pulsed US)

Main outcome variables
1-Spasticity Severity Modified Modified Ashworth Scale (MMAS) Range of Motion 2-Active & Passive Ankle Dorsiflexion 3-Muscle Torque Passive Plantar Flexor Torque 4-Neurophysiology Hmax/Mmax Ratio (H-Reflex Recording) 5-Functional outcome Timed Up and Go test

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260823070769N1**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **prospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date
2026-08-31, 1405/06/09

Registrant information
Name
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Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-09-15, 1405/06/24
Expected recruitment end date
2027-03-15, 1405/12/24
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Extracorporeal Shockwave Therapy and Pulsed Ultrasound on Spasticity neurophysiological and Functional outcomes in Patients with Stroke

Public title
Effect of Shockwave Therapy Versus Ultrasound on Muscle Spasticity After Stroke

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
First-ever stroke. .7 .Stroke duration of at least 6 months and less than 48 months Age 40-70 years. .Ankle plantar flexor MMAS score ≥1 Be able to walk independently Stable vital signs constant drug protocol doses

Exclusion criteria:
Sensation deficits in the foot area . Currently being treated for spasticity . Wound or infection in the affected lower limb . Ultrasound and shockwave contraindications. Radial extracorporeal shock wave therapy (rESWT) contraindications (pregnancy, On major) vessels and nerves, Pacemaker or other implanted devices, Open wounds, Joint Fixed ankle joint contracture . History of Botox . alcohol or phenol block treatments within previous 6 months ago Severe pain with rSWET

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

Gender
Both

Phase
4

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
A total of 30 patients will be randomly assigned into two groups of 15 participants each: the Extracorporeal Shockwave Therapy (ESWT) group and the Pulsed Ultrasound (PUS) group. Both groups will receive treatment 3 sessions per week. Randomization will be performed using a simple randomization method with sealed, opaque envelopes describing the treatment groups. In the first step, the name of each intervention will be written on 15 papers (equal to the sample size of each group) and placed in sealed envelopes. The envelopes will then be mixed, and at the first treatment session, the therapist will draw one envelope randomly to determine the participant’s assigned group and initiate the treatment accordingly.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a single-blinded randomized controlled trial. Due to the nature of the physiotherapy interventions, blinding of the therapist and participants is not possible. However, the outcome assessor is blinded to group allocation. All assessments are performed by an independent assessor who is not involved in treatment and is unaware of the intervention received by participants. Randomization and allocation concealment are performed to minimize assessment bias.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical Sciences

Street address
Mirkhani st.(East Nosrat), Tohid Sq. Tehran

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1419733171

Approval date
2026-08-19, 1405/05/28

Ethics committee reference number
IR.TUMS.FNM.REC.1405.092

Health conditions studied

1

Description of health condition studied
lower limb spasticity after stroke

ICD-10 code
G81.1

ICD-10 code description
Spastic hemiplegia

Primary outcomes

1

Description
severity of spasticity assessed using the MMAS

Timepoint
Primary outcome will be measured at baseline before treatment (T0), immediately after the third treatment session (T1), one week after treatment completion (T2), and one month after treatment completion (T3).

Method of measurement
The patient will be positioned in supine lying with the lower limbs extended, the head in midline, and the upper limbs resting alongside the trunk. The examiner will

stand on the side being tested, placing one hand under the ball of the foot and the other hand stabilizing the limb around the ankle joint. The ankle joint will then be moved from maximum plantar flexion into maximum possible dorsiflexion within approximately one second. The severity of spasticity will be scored from 0 to 4 based on the resistance encountered during passive movement of the ankle plantar flexor muscles, according to the MMAS criteria

2

Description

ankle dorsiflexion range of motion (ROM)

Timepoint

Primary outcome will be measured at baseline before treatment (T0), immediately after the third treatment session (T1), one week after treatment completion (T2), and one month after treatment completion (T3).

Method of measurement

A standard ankle goniometer will be used to assess dorsiflexion range of motion. The patient will be positioned supine with the knee extended and the ankle in a neutral resting position. The fixed arm of the goniometer will be aligned with the longitudinal axis of the leg, while the movable arm will be positioned along the sole of the affected foot. To measure active dorsiflexion, the patient will be instructed to dorsiflex the ankle as far as possible. The same procedure will be used to measure passive ankle dorsiflexion range of motion, except that the physiotherapist will move the ankle through the available range instead of the patient actively performing the movement.

3

Description

Functional outcome.Timed Up and Go (TUG).

Timepoint

Primary outcome will be measured at baseline before treatment (T0), immediately after the third treatment session (T1), one week after treatment completion (T2), and one month after treatment completion (T3).

Method of measurement

1. The participant begins seated in the chair, wearing regular footwear and using their usual walking aid if needed.2. On the command Go the participant stands up and walks at a safe, comfortable pace toward the 3-meter mark.3. After reaching the mark, the participant turns around, walks back to the chair, and sits down.4. Timing: Start the stopwatch on the word Go and stop it when the participant’s buttocks make contact with the seat.

4

Description

Neurophysiological outcomes.H reflex recording:

Timepoint

Primary outcome will be measured at baseline before treatment (T0), immediately after the third treatment session (T1), one week after treatment completion (T2), and one month after treatment completion (T3).

Method of measurement

The electromyography machine will be used to evaluate the maximal H-reflex, the maximal M-wave, and the H-reflex latency. The patient is placed in a prone position with feet off the table. bipolar recording electrodes will be placed on the apex of the triangle formed by the soleus muscle, and the stimulating electrode will be placed 4-5 cm distal from this electrode and will stimulate the posterior tibial nerve in the popliteal fossa. The electromyography (EMG) machine will be set with the band-pass filter at 5 Hz to 3 kHz, sweep speed at 5 msec/div and sensitivity at 500 µV-2 mV/div.

Secondary outcomes

1

Description

passive plantar flexion torque

Timepoint

Primary outcome will be measured at baseline before treatment (T0), immediately after the third treatment session (T1), one week after treatment completion (T2), and one month after treatment completion (T3)

Method of measurement

use a hand-held dynamometer to assess passive plantar flexor torque. The center of the sensitive pad of the dynamometer will be placed on the center of the metatarsal arch in alignment with the head of the third metatarsal, and a fast passive ankle dorsiflexion will be performed. The torque will be assessed. The maximum force obtained will be multiplied by the distance from the third metatarsal head to the ankle joint axis to calculate the maximum torque. Reliability and validity of ankle dynamometry have been confirmed in patients with spasticity

Intervention groups

1

Description

Shock wave group patients will receive 3 sessions of radial extracorporeal shock wave therapy (rESWT)(33, 34) (energy: 60 mJ) with a head applicator 15 mm, 2000 shots, frequency 5 Hz, energy density of 60mj (1 bar), energy applied 0.340 mJ/mm²on myotendinous junction and mid portion of gastrocnemius muscle belly.

Category

Treatment - Devices

2

Description

Intervention group: Ultrasound group . patients will receive 3 sessions of pulsed ultrasound on = 1 ms, off = 9 ms; Duty cycle = 10%) with the following protocol: frequency 1 MHz, intensity 1.5 W/cm², Area of applicator: 5 cm², duration 10 minutes) on the gastrocnemius muscle belly

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
the Physical Therapy Departments of Imam Al HusseinTeaching Hospital

Full name of responsible person
Hussein abdul razzaq Jabbar

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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
Sponsor: country of origin

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
center for hereditary blood diseases

Full name of responsible person
Hussein abdul razzaq jabbar

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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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available