# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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**
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**Recruitment status**
**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

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

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Tehran

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**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**
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## Sponsors / Funding sources

**1**

**Sponsor**

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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

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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