

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jul 2026

### Comparison Study of Effects of Extra Corporeal Shock Wave Therapy and Percussion Massagegun on Pain, Spasm and Performance in Amateur Athletes with subacute Myofascial Pain in Gasterocnemius Muscle

#### Protocol summary

##### Study aim

The efficacy of radial extracorporeal shock wave and percussion massage gun on the pain and performance of young amateur athletes

##### Design

A single-blinded trial with a control group and factorial groups (blinding of outcome-assessor) randomized with an envelope in three treatment groups (n=42)

##### Settings and conduct

The eligible volunteers were sampled, and two researchers are considered as a therapist and an outcome assessor. The subjects are examined, attended in three treatment sessions at the Faculty of Rehabilitation of Tehran University of Medical Sciences, and re-evaluated 3 days after the end of the interventions.

##### Participants/Inclusion and exclusion criteria

Amateur athletes (18-30 years and 19-25 BMI) who suffer from myofascial pain syndrome in the gastrocnemius muscle with at least two-week symptoms are included in the study. The candidates should be devoid of fractures or dislocations in the leg and ankle bones, and injury in tendinomuscular during the last three months.

##### Intervention groups

The study was conducted among three intervention groups which receive three therapeutic sessions. Massage gun group: 5 minute of sweep treatment with level 3 on the muscle bulk and 3 minutes directly on the most painful point in the muscle and trigger point; electrotherapy involving 15 minutes of transcutaneous electrical stimulation (at100Hz and 0.2 ms width pulse) and gasterosuleos stretching with dorsi flexion while standing. Shock wave group: Shock wave (2500-3000 impulses) in the painful area (trigger point or bundle) and 300 impulses in the surrounding tissue; electrotherapy and exercise therapy similar to the first group. Control group: electrotherapy and exercise

therapy similar to the other groups.

##### Main outcome variables

Calf muscle pain, ankle dorsi-flexion and plantar-flexion range of motion, calf muscle strength, and strength performance and general sports performance

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230225057527N1**

Registration date: **2023-03-14, 1401/12/23**

Registration timing: **prospective**

Last update: **2023-03-14, 1401/12/23**

Update count: **0**

##### Registration date

2023-03-14, 1401/12/23

##### Registrant information

##### Name

Seyedeh zohreh Hosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 25 3882 0138

##### Email address

zshosseini1998@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-21, 1402/02/01

##### Expected recruitment end date

2023-09-22, 1402/06/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison Study of Effects of Extra Corporeal Shock Wave Therapy and Percussion Massagegun on Pain, Spasm and Performance in Amateur Athletes with subacute Myofascial Pain in Gastrocnemius Muscle

**Public title**

Comparison of Effects of Extra Shock Wave Therapy and Percussion Massagegun

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Amateur athletes aged 18-30 years with a BMI of 18-25. Pain in the posterior leg muscles (VAS: 3-7) during single-leg movements, affecting the person for at least two weeks. Local pain and tenderness in one or more points, or gastrocnemius muscle bundles in one leg, as well as at least one of the referred pain symptoms related to the TP or muscle bundle (e.g., muscle pain, tingling, and numbness) in the posterior leg muscles, or posterior medial part of ankle, toes, or behind the knee and thigh during rest or active ankle movement, which have limited the person for at least two weeks. Loss of ROM with pain and tissue tension in dorsiflexion movement. No history of systemic disease, especially hypertension, severe liver disease, renal dysfunction, or coagulopathy. No history of the neurological disease of the central nervous system (e.g., spondylolysis, spondylolisthesis, and spinal canal stenosis, and epilepsy). No history of fracture or dislocation in the fibula and tibia bones during the last three months. No history of FX or dislocation in the ankle bones during the last three months. No history of tendinitis or Achilles tendon rupture during the last three months. Patients are physically examined, among whom those with symptoms such as swelling and blackening of the skin, as well as the swelling, stiffness, and pain in the involved vessels were excluded from the study as a case suspected of venous thrombosis. To enter the study, candidates must be devoid of any suspected symptoms of compartment syndrome, including general hardness in the entire involved muscle compartment, decreased pulse at the treatment site and its end, muscle herniation, and walking pattern with ankle pronation. Any extensive and painful echymosis and bruises in the cuff muscle along with a history of severe and sudden trauma or activities (were excluded and subjected a more detailed examination of soft tissue injuries in the area such as cuff contusion and strain of the gastrocnemius and soleus muscles). Patients should have no experience of strong sudden impact or movement along with sudden sharp pain and popping sound in the leg area in the last 3 months. No inflammation or redness or swelling on the site. Lack of wound or skin problems in the treatment site. Lack of active bleeding in the treatment site. Lack of infection in

the treatment site.

**Exclusion criteria:**

Unwillingness to continue the cooperation. Receiving drug or physical intervention at the same time as the treatment period. The patients with MPS who have neurological or atherogenic symptoms such as the symptoms of spinal canal stenosis, and rupture or chronic tendinitis of the Achilles tendon during treatment. Occurring Contraindications to massage (edema, wound, active bleeding, and infection) or contraindications to the use of shock wave (hypertension, wound, new bleeding, skin problems, severe liver disease, epilepsy, renal dysfunction, or coagulopathy) during the study. Any feeling of intense heat in the desired tissue, change in tissue color to dark colors along with increased pain, and any symptoms suggesting the possibility of deep vessel involvement is immediately recorded. The patient is excluded from the routine treatment process and evaluated with the necessary tests. Regarding the patient feeling significant stiffness and hardness in the gastrocnemius muscles along with paresthesia, decreased pulse in the end part of the limb, and other symptoms suggesting the possibility of compartment syndrome during the treatment sessions, the routine treatment is stopped, and the patient is excluded from the study process and subjected to emergency treatment.

**Age**

From **18 years** old to **30 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

To randomize the interventions, three sealed envelopes containing the name of the group are provided to each individual, and without knowing the contents of the envelopes, and the subjects are randomly assigned to one of the treatment groups (massagegun, shock wave, and control) by taking one envelope without knowing its content. Then, the second researcher starts the therapeutic intervention.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

As for blinding, two researchers participate in this study, among whom the first is responsible for the initial and final evaluation of the patients, and another treats the patients without knowing the results of the evaluations.

**Placebo**

Not used

**Assignment**

Factorial

**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

Secretariat of the Committee for Ethics in Biomedical Research of Tehran University of Medical Sciences, Sixth Floor, Central Building of Tehran University of Medical Sciences, West Corner of Ghods St., Keshavarz Blvd., Tehran City, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Approval date

2023-02-23, 1401/12/04

##### Ethics committee reference number

IR.TUMS.FNM.REC.1401.188

## Health conditions studied

### 1

#### Description of health condition studied

Myofascial pain syndrome

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Pre-intervention and 3 days post-intervention

#### Method of measurement

Visual analog scale and assessing point pressure threshold based on algometer

### 2

#### Description

Ankle joint range of motion (dorsi flexion and plantar flexion)

#### Timepoint

Pre-intervention and 3 days post-intervention

#### Method of measurement

Goniometer

### 3

#### Description

Gastrocnemius muscle strength

#### Timepoint

Pre-intervention and 3 days post-intervention

#### Method of measurement

Recording maximum isometric force by using dynamometry in non weight bearing position and single leg plantar flexor rising test in standing position

## Secondary outcomes

### 1

#### Description

General performance

#### Timepoint

Pre-intervention and 3 days post intervention

#### Method of measurement

Lower Extremity Functional Scale (LEFS)

### 2

#### Description

Sport performance (strength performance)

#### Timepoint

Pre-intervention and 3 days after intervention

#### Method of measurement

Single leg triple hop test for distance and vertical jump test

## Intervention groups

### 1

#### Description

Intervention group I: Shock wave with 2500-3000 impulses in the most painful site of muscle and painful, as well as radial shock with 20 Hz and 300 impulses in the surrounding tissue; electrotherapy involving 15 minutes of transcutaneous electrical stimulation (TENS) (100Hz and 0.2 ms width pulse) and standing gastrocnemius stretching with dorsi flexion for one set with 15s hold and eight repetitions, followed by two sets of muscle stretching with 15 s hold and eight repetitions after ending the sessions of shock wave treatment in home

#### Category

Rehabilitation

### 2

#### Description

Control group: electrotherapy involving 15 minutes of transcutaneous electrical stimulation (TENS) (100Hz and 0.2 ms width pulse) and standing gastrocnemius stretching with dorsi flexion for one set with 15s hold and eight repetitions, followed by two sets of muscle stretching with 15 s hold and eight repetitions after ending the sessions of treatment in home

#### Category

Rehabilitation

### 3

#### Description

Intervention group II: Sweep massage of the whole muscle bulk for five minutes at a moderate rate (2400-2700 Hz or level 5 & 6) and direct massage in the most painful site of muscle and painful trigger point for three minutes; electrotherapy involving 15 minutes of transcutaneous electrical stimulation (TENS) (100Hz and 0.2 ms width pulse) and standing gastrocnemius stretching with dorsi flexion for one set with 15s hold and eight repetitions, followed by two sets of muscle stretching with 15 s hold and eight repetitions after ending the sessions of treatment in home

#### Category

Rehabilitation

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

School of Rehabilitation of Tehran University of Medical Sciences

###### Full name of responsible person

Dr Siamak Bashardoust Tajali

###### Street address

School of rehabilitation of Tehran University of Medical Sciences,, Enqelab St., Between Sadi St. & Darvazeh Shemiran, Tehran, Iran

###### City

Tehran

###### Province

Tehran

###### Postal code

11489-65111

###### Phone

+98 21 7753 3939

###### Fax

+98 21 7753 4133

###### Email

Rehabilitation@tums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tehran University of Medical Sciences

###### Full name of responsible person

Hamid Dalvand

###### Street address

Occupational Therapy Department,. Rehabilitation school of Tehran University of Medical Sciences,, Enqelab St., Between Sadi St. & Darvazeh Shemiran, Tehran City

###### City

Tehran

###### Province

Tehran

###### Postal code

11489-65111

###### Phone

+98 21 7762 8205

###### Fax

+98 21 7753 4133

###### Email

hdalvand@sina.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

Seyedeh zohreh Hosseini

###### Position

Master student

###### Latest degree

Bachelor

###### Other areas of specialty/work

Physiotherapy

###### Street address

No. 17, Alley 10, Tohid Blvd., Qom City

###### City

Qom

###### Province

Ghoum

###### Postal code

3713898565

###### Phone

+98 25 3882 0138

###### Fax

###### Email

zshosseini1998@gmail.com

### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Tehran University of Medical Sciences

###### Full name of responsible person

Siamak Bashardoust Tajali

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Physical Therapy Department,. Rehabilitation school  
of Tehran University of Medical Sciences,. Pich  
Shemiran,. Enqelab St., Between Sadi St. & Darvazeh  
Shemiran, Tehran City

**City**

Tehran

**Province**

Tehran

**Postal code**

11489-65111

**Phone**

+98 21 7752 8468

**Fax**

+98 21 7753 4133

**Email**

s\_bashardoust@sina.tums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyedeh zohreh Hosseini

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

No. 17, Alley 10, Tohid Blvd., Qom City

**City**

Qom

**Province**

Ghoum

**Postal code**

3713898565

**Phone**

+98 25 3882 0138

**Fax****Email**

zshosseini1998@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

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**

In this study, the data related to primary and secondary  
outcomes are comparatively shared in tables.

**When the data will become available and for how  
long**

The outcomes are accessible three months after  
publishing the article.

**To whom data/document is available**

Researchers working with the orthopedic and sports  
injuries of ordinary individuals and athletes at different  
levels in academic, sports medicine, and sports  
physiotherapy centers.

**Under which criteria data/document could be used**

The data are allowed to be used in the studies on  
percussion massage gun, shock wave, and myofascial  
pain syndrome assessment, as well as evaluating and  
preparing an optimal treatment protocol for soft tissue  
and muscle disorders.

**From where data/document is obtainable**

The applicants can correspond with Miss Seyedeh Zohreh  
Hosseini, the data manager, via email and request the  
desired data. zshosseini1998@gmail.com

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

To access the study data, applicants should send their  
request containing the need to the data, reason for the  
request, and information indicating their affiliation to a  
university or a related research medical center, as well  
as the generalities of their research. Then, the data  
manager sends the intended data after assessing the  
person's information and its accuracy.

**Comments**