Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Gasterocenemious 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

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Iran (Islamic Republic of)

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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 Gasterocenemious 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

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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
Goniameter

3

Description
Gastrocnemius muscle strength

Timepoint
Pre-intervention and 3 days post-intervention

Method of measurement
Recording maximum isometric force by using dynamometery 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 gasterocnemius 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 gasterocnemius 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 gasterocnemius 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

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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
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
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Physiotherapy

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Person responsible for updating data

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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