Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Comparison of ESWT versus Dry Needling in treatment of myofascial trigger points in calf muscle

Protocol summary

Study aim
Comparing the effects of shock wave therapy and dry needling in reducing the pain of the trigger points of the cuff muscles in order to provide a model for reducing pain in these patients.

Design
A clinical trial with an intervention group and a control group with a sample size of 84 people, as a parallel group, one blind strain, randomized by lottery method.

Settings and conduct
The studied population is patients referred to physical medicine and rehabilitation clinic of Firouzgar Hospital in Tehran. Patients are examined by a physical medicine and rehabilitation specialist and enter the plan if they meet the necessary criteria. This study is a randomized clinical trial with a blind evaluator, who are divided into two groups by lottery.

Participants/Inclusion and exclusion criteria
Conditions for entering the study: 1- Age between 16 and 60 years 2- Patient satisfaction 3-Having at least one active trigger point in the cuff area 4- Duration of symptoms for at least 6 months Exclusion criteria: 1- Presence of neurological defects (weakness, paraesthesia, etc.) 2- History of lumbar discopathy, lumbar disc herniation, myopathy, fibromyalgia, spondylosis, spinal canal stenosis 3- Current drug treatments or physical therapy, surgery and injection in trigger point in the last 6 months 4- Simultaneous painful disorders so that the main complaint of the patient is simultaneous pain 5- Mental disorder 6-Rheumatological diseases

Intervention groups
For the first intervention group, shock wave therapy is performed and for the second intervention group, dry needling is performed.

Main outcome variables
pain and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230801058995N1**
Registration date: **2023-10-03, 1402/07/11**
Registration timing: **prospective**

Last update: **2023-10-03, 1402/07/11**
Update count: **0**

Registration date
2023-10-03, 1402/07/11

Registrant information
Name
Reza Shokri koltapeh
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of ESWT versus Dry Needling in treatment of myofascial trigger points in calf muscle

Public title

Comparison of ESWT versus acupuncture in treatment of myofascial trigger points in calf muscle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 16 and 60 years Patient satisfaction Having at least one active trigger point in the cuff area Duration of symptoms for at least 6 months

Exclusion criteria:

Presence of neurological defects (weakness, paresthesia, etc.) History of lumbar discopathy, lumbar disc herniation, myopathy, fibromyalgia, spondylosis, spinal canal stenosis Current drug treatments or physical therapy, surgery and injection in trigger point in the last 6 months Simultaneous painful disorders so that the main complaint of the patient is simultaneous pain Mental disorder Rheumatological diseases

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into intervention and control groups by randomization method in the form of lottery. In this way, based on the number of samples, half of the lots will receive only shockwave and the other half will receive dry needling. Then, one lot will be drawn for each patient by the person performing it (physical medicine and rehabilitation assistant) who will be constant and not the evaluator of the research. And the intended intervention is implemented for the patient

Blinding (investigator's opinion)

Single blinded

Blinding description

The method of blinding for the analyzer is that the selected intervention for each patient is written in the demographic questionnaire using a lottery by the person performing it, and the analyzer is written on the way of grouping and the type of treatment selected for the patients until the end of the 6-month evaluation. will not be aware.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

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Hemat Highway next to Milad Tower، 14535

City

Tehran

Province

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Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-09-28, 1401/07/06

Ethics committee reference number

IR.IUMS.FMD.REC.1401.360

Health conditions studied

1

Description of health condition studied

Myofascial trigger point

ICD-10 code

M79.1

ICD-10 code description

Myalgia

Primary outcomes

1

Description

Pain variable is evaluated by two scales.PPT is calculated by using a digital algometer by applying vertical pressure to the trigger points. In order to stimulate the patient's pain, the pressure is increased at a rate of 1Kg/Cm2/s and the subjective reports of the people are recorded. The place of maximum pain is at a distance of 1 minute will be checked again.Visual analog scale (VAS) measures the intensity of the patient's pain. Validation and reliability studies have been done. The VAS scale is divided into 10 vertical or horizontal lines from zero (no pain) to 10 points (the most severe pain).n of general health, vitality, social role function, limitation in emotional function and health. It is fluent. The checklist is attached.Visual analog scale (VAS) measures the intensity of the patient's pain. Validation and reliability studies have been done. The VAS scale is divided into 10 vertical or horizontal lines from zero (no pain) to 10 points (the most severe pain).

Timepoint

VAS and PPT variables are completed for each patient immediately after completing three sessions of shock

wave and dry needling, and then one month and three months after the completion of the interventions. Also, the VAS variable is checked again six months after the end of the interventions

Method of measurement

PPT is calculated using a digital algometer (Brandwagner) by applying vertical pressure to the trigger points. In order to stimulate the patient's pain, the pressure is increased at a rate of 1 Kg/Cm2/s and the subjective reports of the people are recorded.The VAS scale is divided into 10 vertical or horizontal lines from zero (no pain) to 10 points (the most severe pain).

Secondary outcomes

1

Description

The quality of life is measured by the 36-item short form (SF-36), which is the most widely used general quality of life scale in the medical field. It includes 8 sub-categories, which are 36 items in total, and evaluates physical and mental health in general. The sub-categories include physical function, difficulty in performing physical activity, pain, perceptio

Timepoint

It is completed immediately after three sessions of shock wave and dry needling, and then one month and three months after the completion of the interventions for each patient.

Method of measurement

In this study, the quality of life is calculated by the SF-36 questionnaire.

Intervention groups

1

Description

The first intervention group is subjected to shockwave therapy, which is provided once a week for three consecutive weeks. Shockwave therapy using Storz medical masterpulse MP100 device is applied in each session with settings: intensity 1.5 to 3 times, 1000 impulses in the trigger point area and 500 impulses around and 10 Hz frequency and for 3-4 minutes.

Category

Treatment - Devices

2

Description

In the dry needling group, the treatment will be done with disposable dong-bang stainless steel needles in sizes 0.25 x 0.4 after sterilizing the needle insertion site in painful points with alcohol cotton. The needles are inserted through the guide tube in the specified painful points, and the depth of the needles is 15-30 mm, and they remain in place for 20 minutes in each session, and at the 10th minute, the needles are rotated for re-stimulation.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Firouzgar Hospital, Tehran

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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
Iran 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
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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The rate of improvement of the patient's pain can be shared based on the Visual Analogue Scale and pain pressure threshold
When the data will become available and for how long
Access starts from 1404
To whom data/document is available
Study data will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Access to the data for epidemiological investigation and study will be allowed and can be sent via email.
From where data/document is obtainable
To get the data, you can call 00989183769745 via mobile phone or contact via email rezashokri70@gmail.com.
What processes are involved for a request to access data/document
People applying for data should send their academic and scientific documents and the reason for their request to rezashokri70@gmail.com.
Comments