# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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

**Street address**

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

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## Sponsors / Funding sources

### 1

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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**
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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**