

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Extracorporeal shock wave therapy versus phonophoresis therapy for myofascial pain syndrome of neck: A randomized clinical trial

#### Protocol summary

##### Study aim

Considering high prevalence of neck pain and myofascial pain syndrome in this region, this study aimed to compare the efficacy of phonophoresis with hydrocortisone gel and ESWT on pain and physical disability in patients with myofascial pain of neck.

##### Design

A clinical trial with two parallel group, randomized and blinded outcome assesment of 40 patients. Randomization was allocated by Random Allocation software.

##### Settings and conduct

This study has been double blinded ,which physician who evaluates VAS and NDI and data analyzer epidemiologist are blinded. This study is conducted in Isfahan university clinics in this city.

##### Participants/Inclusion and exclusion criteria

Patients older than 18 years old were included in the study if they had pain in at least one active trigger point located in the upper trapezius muscle for at least 6 month. The exclusion criteria were treatment program for neck or shoulder pain during the last two months, neck or shoulder surgery during the last two years, neck radiculopathy, trauma history, presence of cardiovascular, respiratory or allergic disease, neck osteoarthritis, presence of coagulation disorders and pregnancy.

##### Intervention groups

Twenty patients were assigned to ESWT group and 20 assigned to phonophoresis group. Patients in both groups received same stretching exercise program for upper trapezius muscles and drug regimen included tizanidine and meloxicam for three weeks. The ultrasound was done in phonophoresis group using ultrasound device by application of hydrocortisone gel 1% over the trigger point on trapezius muscle. In this group therapies were applied three times a week for 3 weeks. Patients in ESWT group received three session of ESWT, once a week for three weeks.

##### Main outcome variables

Improvement of symptoms of patients which is evaluated by VAS and NDI questionnaire.

#### General information

##### Reason for update

##### Acronym

.ESWT vs phonophoresis therapy for MPS of neck

##### IRCT registration information

IRCT registration number: **IRCT20190618043931N2**

Registration date: **2020-10-24, 1399/08/03**

Registration timing: **retrospective**

Last update: **2020-10-24, 1399/08/03**

Update count: **0**

##### Registration date

2020-10-24, 1399/08/03

##### Registrant information

##### Name

Shila Haghghat

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3627 5139

##### Email address

shila\_haghghat@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-08, 1397/07/16

##### Expected recruitment end date

2019-02-20, 1397/12/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Extracorporeal shock wave therapy versus phonophoresis therapy for myofascial pain syndrome of neck: A randomized clinical trial

**Public title**

Extracorporeal shock wave therapy versus phonophoresis therapy for myofascial pain syndrome of neck

**Purpose**

Treatment

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

Patients with myofascial pain of neck older than 18 years old who had pain in at least one active trigger point located in the upper trapezius muscle For at least 6 month

**Exclusion criteria:**

Treatment program for neck or shoulder pain during the last two months Neck or shoulder surgery during the last two years Neck radiculopathy Trauma history Presence of cardiovascular, respiratory or allergic disease, neck osteoarthritis, presence of coagulation disorders Pregnancy

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients with myofascial pain syndrome in neck were randomly assigned into two groups. Randomization was allocated by Random Allocation software. Random Allocation Software is a program created by Microsoft. Once this software is installed and run, could be adjusted in some options. We set it for 2 groups, sample size of 40, random size of blocks and for an output file with numeric codes. Then program produces a random sequence of numbers which will be used for grouping of patients. By using this software twenty patients were assigned to ESWT group and 20 assigned to phonophoresis group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study the physician who evaluates VAS criteria and Neck Disability Index of the patients (out put) will not know anything about the therapeutic method which

is used for patients. In addition data analyzer epidemiologist was informed about treatment groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of MedicalSciences

**Street address**

Hezar Jarib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2018-10-08, 1397/07/16

**Ethics committee reference number**

IR.MUI.MED.REC.1397.094

**Health conditions studied****1****Description of health condition studied**

Myofascial pain syndrome of neck: Myofascial pain syndrome is regional pain condition of skeletal muscle fibers characterized by the presence of myofascial trigger points. Trigger points of upper trapezius muscle are one of the common reasons of neck and upper limbs pain.

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Pain and quality of life in patients with myofascial pain syndrome of neck

**Timepoint**

Before the intervention ,immediately and 4 weeks after intervention in each group

**Method of measurement**

Pain intensity using VAS criteria and quality of life using NDI questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: The ultrasound is done in phonophoresis group using ultrasound device by application of hydrocortisone gel 1%. In this group therapies were applied three times a week for 3 weeks.

#### Category

Treatment - Devices

### 2

#### Description

Intervention group 2: Patients in ESWT group received three sessions of ESWT , three times a week for three weeks. Patients in both groups received same stretching exercise program for upper trapezius muscles and drug regimen included tizanidine at bed time and meloxicam (7.5 mg/day) for three weeks.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinic of Physical medicine affiliated with the Isfahan medical sciences university

##### Full name of responsible person

Marzie Naderi

##### Street address

Al-Zahra Hospital ,Shohadaye Sofeh Ave.

##### City

Isfahan

##### Province

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##### Postal code

73461-81746

##### Phone

+98 31 3668 3148

##### Email

MN100000@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Ziba Farajzadegan

##### Street address

Isfahan University of Medical Sciences,Hezar Jarib

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farajzadegan@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

##### Full name of responsible person

Marzie Naderi

##### Position

Consultant

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physical Medicine

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## Person responsible for scientific inquiries

#### Contact

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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

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

A portion of the information, such as information on the main outcome or the like, can be shared.

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

Starting the access period 6 months after printing results

### To whom data/document is available

Researchers working in academic institutions

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

No specific conditions

### From where data/document is obtainable

Contact with author and researcher

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

By emailing or calling the author as soon as you respond to data requestor, you can access the data

### Comments