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 Haghighat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3627 5139

Email address

shila_haghighat@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
Exteracorporal 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 myofacial 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 physicion 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 epidemiologis 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
Isfehan
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: Myofacial 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 sydrome 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ziba Farajzadegan
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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 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