Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effects of Extracorporeal ShockWave Therapy and conventional physiotherapy in improvement of patients with shoulder girdle myofascial pain syndrome.

Protocol summary

Summary

Objective: in this study we want to campare the effects of Extracorporeal ShockWave Therapy and conventional physiotherapy in improvement of patients with shoulder girdle myofascial pain syndrome. Design: double- blinded randomized clinical trial without placebo. Among the patients that refer to physical medicine and rehabilitation clinic, those with myofascial pain syndrome diagnosis that have inclusion criteria will enrolled into the study. inclusion criteria:age between 20 to 55 years old, presence of palpable taut band at physical examination, pain for at least 2 months, severity of pain at least 30 millimeters in Visual Analogue Scale , normal neurologic examination, absence of other diseases such as radiculopathy, absence of shoulder injection in recent 2-3 months, absence of dry needling injection, absence of shockwave contraindications. Exclusion criteria: patients with psychotic disorders such as depression and anxiety that take treatment and patients that do not finish the course of teratment or do not refer for follow up.Sample size is 66 patients from both sex that randomly will divide into 3 groups. First group will take Shockwave therapy with shockwave instrument(2000 impulses,5Hz,EFD=0.1 mj/mm2) for 3 sessions(1 session per week) with stretch exercises of shoulder muscles at home for 20 days(twice a day). Second group will take Routine physiothrapy for 10 sessions(3 sessions per week) with stretch exercises of shoulder muscles at home for 20 days(twice a day).physiotherapy includes: hot pack for 20 minutes with heat of 74.5 degrees celsius. Electrical nerve stimulation with frequencies of 70 to 80 hertz for 25 minutes. Continuous ultrasonography with dose of 1.25 to 1.5 w/cm2 . Third group will treat with stretch exercises of shoulder for 20 days(twice a day). Patients before treatment, immediately after treatment and one month after treatment will evaluate for these outcomes: pain with Visual Analogue Scale, Pain Pressure Treshold with algometer device, Ability to manage in erveryday life with Neck Disability index questionnaire, Range of motion of shoulder joints with goniometer, Range of motion of neck with inclinometer device and Shoulder muscle forces through physical examination.Outcomes will analyze with statistical methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201608154104N5**
Registration date: **2016-09-25, 1395/07/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-09-25, 1395/07/04

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research center of Physical Medicine and Rehabilitation,Tabriz university of medical sciences

Expected recruitment start date
2016-10-22, 1395/08/01
Expected recruitment end date
2018-03-20, 1396/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of Extracorporeal ShockWave Therapy and conventional physiotherapy in improvement of patients with shoulder girdle myofascial pain syndrome.

Public title
Comparison of the effects of ShockWave Therapy and physiothreapy in teratment of muscular pain of shoulder.
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: age between 20 to 55 years old,at physical examination presence of palpable taut bands along that there are one or more trigger points that pressure on them causese pain , pain at least for 2 months, severity of pain at least 30 millimeters in Visual Analogue Scale, normal neurologic examination, absence of other diseases(such as radiculopathy,severe osteoarthritis, rheumatic disese) that will be ruled out with blood tests, simple graphy,MRI and electrodiagnostic studies, Absence of recent accident and recent surgery and fracture of spinal column, absence of shoulder injection in recent 2-3 months, absence of dry needling injection, absence of shockwave contraindications(hemorrhagic disorders, use of anticoagulants,thrombosis, tumors, cardiac pacemaker, pregnancy, diabetic polyneuropathy), Exclusion criteria: absence of inclusion criteria and patients with psychotic disorders such as depression and anxiety that take treatment and patients that do not finish the course of teratment or do not refer for follow up.
Age
From **20 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The patients will divide randomly into 3 groups (A,B,C).For randomization we will use computerized randomization with Excel software and we will write this sequence in separate pockets and put them in a box. The patients will treat with sequence of this box.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Daneshgah Ave., executive field of Tabriz University of Medical Sciences, vice chancellor for research of Tabriz university of medical Sciences,Ethics committee.
City
Tabriz
Postal code
Approval date
2016-07-04, 1395/04/14
Ethics committee reference number
IR.TBZMED.REC.1395.297

Health conditions studied

1

Description of health condition studied
Muscular pain syndrome
ICD-10 code
M75.9
ICD-10 code description
Shoulder lesion, unspecified

Primary outcomes

1

Description
Pain
Timepoint
before treatment, immediately after treatment and one month after treatment.
Method of measurement
Visual Analogue Scale with grading from zero to 100 millimeters.

2

Description
Pain Pressure Treshold
Timepoint

before treatment, immediately after treatment and one month after treatment.

Method of measurement

Algometer device

3

Description

Ability to manage in erveryday life.

Timepoint

before treatment, immediately after treatment and one month after treatment.

Method of measurement

Neck Disability index questionnaire

Secondary outcomes

1

Description

Range of motion of shoulder joints

Timepoint

before treatment, immediately after treatment and one month after treatment.

Method of measurement

Goniometer

2

Description

Range of motion of neck

Timepoint

before treatment, immediately after treatment and one month after treatment.

Method of measurement

Inclinometer device

3

Description

Shoulder muscle forces

Timepoint

before treatment, immediately after treatment and one month after treatment.

Method of measurement

Physical examination

Intervention groups

1

Description

Shockwave therapy with shockwave instrument(2000 impulses,5Hz,EFD=0.1 mj/mm2) for 3 sessions(1 session per week) with stretch exercises of shoulder muscles at home for 20 days(twice a day).

Category

Treatment - Devices

2

Description

Routine physiothrapy for 10 sessions(3 sessions per week) with stretch exercises of shoulder muscles at home for 20 days(twice a day).physiotherapy includes: hot pack for 20 minutes with heat of 74.5 degrees celsius. Electrical nerve stimulation with frequencies of 70 to 80 hertz for 25 minutes. Continuous ultrasonography with dose of 1.25 to 1.5 w/cm2

Category

Rehabilitation

3

Description

The third group will do stretch exercises of shoulder for 20 days(twice a day).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza University Hospital

Full name of responsible person

Dr. Mohammad Rahbar

Street address

Golgasht Ave.,Imam Reza university hospital,Physical medicine and rehabilitation ward

City

Tabriz

2

Recruitment center

Name of recruitment center

Shohada Educational Center

Full name of responsible person

Dr.Maryam Samandarian

Street address

Golshahr Ave,Elgoli,Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research center of Physical Medicine and Rehabilitation,Tabriz university of medical sciences

Full name of responsible person

Dr. Neda Dolatkhah

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Golgasht Ave,Imam Reza hospital, research center of Physical medicine and rehabilitation,Tabriz

City

Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research center of Physical Medicine and Rehabilitation,Tabriz university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty