

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 compare 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 treatment 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 physiotherapy 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 Threshold with algometer device, Ability to manage in everyday 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

Mohammad Rahbar

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 physiotherapy in treatment 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 causes 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 disease) 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 treatment 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 Threshold

Timepoint

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

Method of measurement

Algometer device

3

Description

Ability to manage in everyday 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 physiotherapy 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

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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 Dolatkah

Street address

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

Contact

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

Maryam Samandarian

Position

Physical medicine and rehabilitation resident

Other areas of specialty/work

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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