

# 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/mm<sup>2</sup>) 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/cm<sup>2</sup> . 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1544 6694

##### Email address

rahbarm@tbzmed.ac.ir

##### 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/mm<sup>2</sup>) 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/cm<sup>2</sup>

**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 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**

**Street address**

Golgasht Ave, Imam Reza hospital, Physical medicine and rehabilitation department.

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3337 3967

**Fax**

**Email**

dr.marsam17@gmail.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Rahbar

**Position**

Assistant professor of Physical Medicine & rehabilitation

**Other areas of specialty/work**

**Street address**

Golgasht Ave., Imam Reza Hospital, Department of Physical Medicine and rehabilitation

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3337 3967

**Fax**

**Email**

rahbarm@tbzmed.ac.ir

**Web page address**

**Person responsible for updating data**

**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**

**Street address**

Golgasht Ave, Imam Reza hospital, Physical medicine and rehabilitation department

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3337 3967

**Fax**

**Email**

dr.marsam17@gmail.com

**Web page address**

**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*