

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The Comparison of the effectiveness of Piroxicam mesotherapy versus Using Extracorporeal Shock Wave Therapy (ESWT) in Reducing Pain and Improving Function in Patients with rotator cuff tendinopathy

Protocol summary

Study aim

The Comparison of the effectiveness of Piroxicam mesotherapy versus Using Extracorporeal Shock Wave Therapy (ESWT) in Reducing Pain and Improving Function in Patients with rotator cuff tendinopathy

Design

The study is a double-blind randomized clinical trial on 60 patients with a control group.

Settings and conduct

The samples were selected from patients with non-specific shoulder pain (rotator cuff tendinopathy) referred to Imam Reza Clinic and Rajaei Hospital and divided into two groups. A randomized block method is used and the study begins after obtaining written consent. In the control group, shockwave therapy is performed, and in the intervention group, we perform piroxicam mesotherapy, and finally we measure their effect in reducing pain and improving patients' performance.

Participants/Inclusion and exclusion criteria

Entry requirements: age over 18 years, completion and signing of the consent form, shoulder pain lasting more than 4 weeks with a Visual analogue scale of at least 4 in the last month, absence of any disease around the relevant shoulder joint. Exclusion conditions: Peripheral and central nervous system diseases and severe musculoskeletal disorders and uncontrolled internal diseases. Failure to comply with entry requirements

Intervention groups

group A receives the shock wave. group B receives piroxicam in the form of mesotherapy in the involved shoulder and

Main outcome variables

Pain level, performance of patients in daily life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220903055865N1**

Registration date: **2022-10-02, 1401/07/10**

Registration timing: **prospective**

Last update: **2022-10-02, 1401/07/10**

Update count: **0**

Registration date

2022-10-02, 1401/07/10

Registrant information

Name

Fateme Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-07, 1401/07/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effectiveness of Piroxicam mesotherapy versus Using Extracorporeal Shock Wave Therapy (ESWT) in Reducing Pain and Improving Function in Patients with rotator cuff tendinopathy

Public title

Comparing the effectiveness of shock wave therapy and mesotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Completing and signing the consent form Patients with shoulder pain lasting more than 4 weeks Shoulder pain with an Oxford shoulder score of at least 4 in the last month Age over 18 Absence of any type of disease around the relevant joint

Exclusion criteria:

Any pathology found on the plain radiograph, including degenerative findings of the shoulder joint Any clinical symptoms of effusion, inflammation, redness and warmth of the shoulder Having diabetes, uncontrolled blood pressure and rheumatic and vascular collagen diseases such as lupus, gout and simultaneous radiculopathy, myopathy, nerve damage and neuropathies such as carpal tunnel syndrome, stroke and any type of systemic infection. Body mass index above 42 History of joint replacement and trauma and fracture on the side of the involved shoulder Suffering from bleeding diseases and taking anticoagulant drugs Psychological problems Any hypersensitivity to drugs used in the study, such as piroxicam History of significant heart, kidney, liver, brain, lung disorders History of injections in or around the affected shoulder joint in the last 3 months History of shoulder and upper limb physiotherapy in the last one month Pregnant and lactating woman Cancer

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to match the patients of the intervention and control groups, the patients are randomly divided. To perform randomization in this research, permutation block method with 4 samples in each block is used and the randomization list is obtained using Random Allocation software. We will have two lists of 30 people including intervention and control groups randomly. In order to hide the random sequence method, another

person who is unaware of the research process is presented and the questionnaires are completed by a person who is unaware of the division of groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: In this study, we do not have the ability to blind the patient, because the patients of both interventions know the type of intervention. Clinical caregiver: We teach the person who is in charge of the care and follow-up of the patients how to complete the questionnaire. This person has no knowledge of the type of patient intervention. Researcher: In this study, we do not have the ability to blind the researcher, because the researcher conducts both studies himself and knows the type of intervention received in each group. Outcome evaluator: Completed questionnaires are given to a person who does not know about the interventions and he is asked to determine the amount of pain reduction and performance increase in each person according to the questionnaire. Data analyst: Finally, after completing and collecting all the information, the questionnaires are given to a person to check the information, who does not know about any of the work steps and how the intervention is divided.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Unit 1, No. 50, Peyman Building, Shahid Rajaei Boulevard, Farhang Shahr, Shiraz, Iran

City

Shiraz

Postal code

7185964655

Approval date

2022-08-21, 1401/05/30

Ethics committee reference number

IR.SUMS.MED.REC.1401.247

Health conditions studied

1

Description of health condition studied

Shoulder Rotator cuff tendinopathy(Non-specific shoulder pain)

ICD-10 code

M25.519

ICD-10 code description

Pain in unspecified shoulder

Primary outcomes**1****Description**

Shoulder pain

Timepoint

Before intervention; Two weeks, four weeks, eight weeks and twelve weeks later

Method of measurement

Visual analogue scale, Oxford shoulder score

Secondary outcomes**1****Description**

Patient performance

Timepoint

Before intervention; Two weeks, four weeks, eight weeks and twelve weeks later

Method of measurement

Oxford shoulder scale

Intervention groups**1****Description**

Intervention group: group A : Treatment of group A is to perform shock therapy session (ESWT) with frequency 10 and impulse 1000, intensity 2 to 3 based on patient tolerance, once a week for 6 weeks at the site of shoulder injury and correct lifestyle and exercise appropriate shoulder pain .Before entering the study and 2, 4, 8, and 12 weeks after the intervention, the patients completed the visual analog scale questionnaires and the Oxford shoulder score.

Category

Rehabilitation

2**Description**

Control group: group B : subcutaneous injection of 1 ml of piroxicam 20 mg along with 4 ml of lidocaine 2% in the painful points and around the involved shoulder at a distance of at least 1 cm. Mesotherapy is performed in 3 stages with a one-week interval according to a common and sterile protocol along with the recommendation to follow the correct lifestyle and perform appropriate exercises for shoulder pain. Before entering the study and 2, 4, 8, and 12 weeks after the intervention, the patients completed the visual analog scale questionnaires and the Oxford shoulder score.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Rehabilitation Clinic

Full name of responsible person

Mani ramzi

Street address

Namazi square

City

Shiraz

Province

Fars

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714737-71348

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+98 71 3212 7700

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Younes ghasemi

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in front of Ma'aref School , khalili St

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fateme nazari

Position

Extern

Latest degree

A Level or less

Other areas of specialty/work

Others

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fateme nazari

Position

University student(extern)

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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

All available data can be shared after de-identifying people

When the data will become available and for how long

Access starts one year after results are published

To whom data/document is available

Everyone will have access to this information.

Under which criteria data/document could be used

If the information of this study helps in improving the process of science

From where data/document is obtainable

Fateme nazri/ 00989164900466

W.faezenazari98@yahoo.com

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

After sending the desired message, we will talk with all the authors of this study and if necessary, all the information will be sent within a maximum of three weeks.

Comments