Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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 caff 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 caff 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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+98 71 3633 3973

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stud6810016317@sums.ac.ir

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 caff 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 Rajaee 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
Postal code
714737-71348
Phone
+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
Street address
in front of Ma'aref School ، khalili St
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Phone
+98 71 3628 1506
Fax
Email
Info@sums.ac.ir
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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Position
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Person responsible for updating data

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Position
University student(extern)

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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

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Email
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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