Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The Comparison of the Effectiveness of Piroxicam Mesotherapy versus Ultrasound-Guided Corticosteroid Injection in Reducing Pain and Improving Function in Patients with Non Specific Shoulder Pain

Protocol summary

Study aim
Comparison of piroxicam mesotherapy with ultrasound-guided corticosteroid injection in reducing pain and improving function in patients with non specific shoulder pain

Design
The research is a randomized double blind clinical trial on 58 patients

Settings and conduct
Samples are selected from patients with non specific shoulder pain referred to Imam Reza Clinic and Rajaee Hospital divided into two groups The blocked randomized method is used. After obtaining informed consent, In control group corticosteroid is injected under guide of ultrasound and in intervention group piroxicam mesotherapy is done Finally effects on pain reduction and functional improvement are measured

Participants/Inclusion and exclusion criteria
Inclusion criteria:Age over 18 y/o Shoulder pain lasted more than 4 weeks with VAS score of at least 4 in a recent month Absence of any disease around the shoulder joint Exclusion criteria:Any pathology on radiograph Degenerative shoulder joint Clinical signs of inflammation in affected shoulder Diabetes Mellitus Uncontrolled hypertension Rheumatic and collagen vascular diseases Lupus Gout Radiculopathy Myopathy Nerve injuries Neuropathy Stroke Infection Brucellosis BMI above 42 Shoulder joint replacement on the affected side Hx of shoulder trauma,fracture Severe deformities of the upper limbs Bleeding disorders Use of anticoagulants Mental Psychological problems Hx of allergies to the used drugs Hx of significant liver, kidney, brain, cardiopulmonary disorders Hx of intraarticular or periarticular injections at the affected joint in the last 3 months Hx of shoulder and upper limb physiotherapy in the last 1 month Pregnancy Lactating Malignancy

Intervention groups
Group A undergoes piroxicam mesotherapy in the affected shoulder Group B undergoes local corticosteroid injection using ultrasound guide in the affected shoulder

Main outcome variables
Pain, Activity of daily living

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210423051050N1**
Registration date: **2021-05-11, 1400/02/21**
Registration timing: **prospective**

Last update: **2021-05-11, 1400/02/21**
Update count: **0**

Registration date
2021-05-11, 1400/02/21

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-21, 1400/03/31

Expected recruitment end date
2022-01-20, 1400/10/30

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 Ultrasound-Guided Corticosteroid Injection in Reducing Pain and Improving Function in Patients with Non Specific Shoulder Pain

Public title
Evaluation of the Effect of Subcutaneous Injection of Piroxicam in Patients with Non Specific Shoulder Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years of age Male or Female gender Completing and signing the informed consent form Patients with shoulder pain lasted more than 4 weeks and with a shoulder pain Visual Analog Scale (VAS) score of at least 4 in a recent month Absence of any disease around the affected shoulder joint
Exclusion criteria:
Any pathology found on plain radiograph such as degenerative findings of the shoulder joint Any clinical signs of effusion, inflammation, redness and warmth of the affected shoulder Diabetes Mellitus Uncontrolled Hypertension Rheumatic and Collagen Vascular Diseases such as Lupus and Gout Concomitant Radiculopathy (cervical radiculopathy), Myopathy, Nerve injuries and Neuropathies (including CTS) Stroke Any serious systemic and local infection Brucellosis BMI above 42 History of shoulder joint replacement on the affected side History of shoulder trauma and fracture and severe deformities of the upper limbs Bleeding tendency and bleeding disorders and/or use of anticoagulants Inability to communicate and complete questionnaires (Mental and Psychological problems) History of allergies and allergic reactions to the used drugs including piroxicam, corticosteroids and lidocaine History of significant liver, kidney, brain and cardiopulmonary disorders History of intraarticular or periarticular injections at the affected shoulder joint in the last 3 months History of shoulder and upper limb physiotherapy (physical therapy) in the last 1 month Pregnant and Lactating women Patients with Cancer or Malignancy
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: **58**
Randomization (investigator's opinion)
Randomized
Randomization description
To match patients in the intervention and control groups, patients are randomly assigned to one of two treatment groups. The random allocation method in this study will be the permutation blocks randomization method with 4 samples in each block and a random list of data will be obtained by using Random Allocation software. We will have two lists of 29 patients, including the two intervention and control groups, at random. For concealment, method of random sequencing is given to another person who is unaware of the research process, and the questionnaires are completed by a person unaware of the division of groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participant: in this study, we does not have the ability to blind the participant because the participant is aware of receiving each intervention. Clinical care giver: we teach the caregiver how to complete the questionnaire. This person is not aware of receiving patient’s intervention. Researcher: this study does not have the ability to blind the researcher due to performing both interventions by himself and being aware of receiving the kind of intervention in each group. The outcome assessor of the complete questionnaires is given to a person who is not aware of the intervention performed and he/she is asked to determine the level of performance in each person according to the questionnaires. Data analyzer: questionnaire are finally given to a person to review the information. This person does not know any of the steps of the work and the way of classification in which the intervention performed.
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
6th Alley, Takestan Ave., Shahid Rajaei Blvd.
City
Shiraz
Province
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Postal code
7185988717

Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
IR.SUMS.MED.REC.1400.051

Health conditions studied

1

Description of health condition studied
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
Function of patient
Timepoint
Before intervention; two weeks, four weeks, eight weeks and twelve weeks later
Method of measurement
Oxford Shoulder Score

Intervention groups

1

Description
Intervention group: Subcutaneous injection (mesotherapy) of 1 ml piroxicam 20 mg/ml with 4 ml lidocaine 2% is applied in tender points of the affected shoulder and around the affected shoulder as a grid pattern where each point was at least 1 cm away from the others. Mesotherapy is performed in 3 sessions at intervals of one week according to the common and sterile protocol along with lifestyle modification and doing appropriate exercises for shoulder pain. The patients have to complete the Visual Analog Scale and Oxford Shoulder Score questionnaires before entering the study and 2,4,8 and 12 weeks after intervention.
Category
Rehabilitation

2

Description
Control group: Injection of 1 ml corticosteroid methylprednisolone acetate 40 mg/ml with 4 ml lidocaine 2% is applied locally at the site of the lesion and in the affected shoulder under guide of ultrasonography. Corticosteroid injection is performed in one session according to the common and sterile protocol along with lifestyle modification and doing appropriate exercises for shoulder pain. The patients have to complete the Visual Analog Scale and Oxford Shoulder Score questionnaires before entering the study and 2,4,8 and12 weeks after intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza rehabilitation clinic
Full name of responsible person
Mani Ramzi
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2

Recruitment center
Name of recruitment center
Rajaee hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Phone
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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
Mohammad Hossein Jabbedari
Position
Resident
Latest degree
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Physical Medicine
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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 making people unidentifiable.

When the data will become available and for how long

Start access period one year after publishing the results.

To whom data/document is available

Everyone can access to this information.

Under which criteria data/document could be used

If the information in this study helps to improve the science process.

From where data/document is obtainable

Dr. Mohammad Hossein Jabbedari, 00989389443577 , ja.mohammadh@gmail.com

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

After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of three weeks if permitted.

Comments