

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 2026

### Comparison of the Effectiveness of Methyl Prednisolone Acetate Injection at the Jianqian Acupoint versus Oral Piroxicam in Reducing Pain and Improving Function in patients with Non Specific Shoulder Pain

#### Protocol summary

##### Study aim

Comparison of the effect of Methyl Prednisolone Acetate injection at the Jianqian acupoint versus oral Piroxicam in reducing pain and improving function in patients with non specific shoulder pain

##### Design

Study of a clinical trial with a control group, with parallel groups, double-blinded, randomized on 58 patients. There is no trial phase. Permutation block is used for randomization.

##### Settings and conduct

The samples are selected from patients with non-specific shoulder pain referred to Imam Reza Clinic and Rajaei Hospital and divided into two groups. Blocked random method is used and the study begins after obtaining informed consent. We give oral Piroxicam for control group and inject Methyl Prednisolone acetate at the Jianqian acupoint for the intervention group. Finally effect on pain reduction, functional improvement and range of motion of shoulder are measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-specific shoulder pain lasted more than 6 weeks with active movement restriction in at least one plane Exclusion criteria: Any infection and inflammation, Acute trauma, Fractures, Dislocations, History of allergy to drugs, Any contraindications for the used drugs, Pregnant, Lactating, Malignancy, History of injection or physical therapy in the past month, Active rheumatism, Uncontrolled hypertension, Diabetes Mellitus

##### Intervention groups

Intervention Group: A mixture of 40 mg Methyl Prednisolone Acetat and 4 cc Lidocaine 2% is injected at Jianqian acupoint. Control Group: This group takes 10mg Piroxicam capsules twice daily for 2 weeks.

##### Main outcome variables

Pain; Range of motion of shoulder; Function of patient

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220718055488N1**

Registration date: **2022-07-28, 1401/05/06**

Registration timing: **prospective**

Last update: **2022-07-28, 1401/05/06**

Update count: **0**

##### Registration date

2022-07-28, 1401/05/06

##### Registrant information

##### Name

Lale Zare

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3621 2959

##### Email address

dr.lalezare@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-08-06, 1401/05/15

##### Expected recruitment end date

2023-02-20, 1401/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison of the Effectiveness of Methyl Prednisolone Acetate Injection at the Jianqian Acupoint versus Oral Piroxicam in Reducing Pain and Improving Function in patients with Non Specific Shoulder Pain

**Public title**

Effect of Methyl Prednisolone Acetate injection at the Jianqian Acupoint in Patients with Non Specific Shoulder Pain

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients over 18 years old Non-specific shoulder pain lasted more than 6 weeks Limitation of active range of motion in at least one plane Absence of any disease around the affected shoulder Completing and signing the informed consent

**Exclusion criteria:**

Any systemic or local infection Acute trauma Fracture or Dislocation Malignancy Liver or Renal failure Gastrointestinal disease, Cardiovascular disease, Asthma, DM, uncontrolled HTN History of injection or physical therapy during the last month Clinical symptoms of inflammation or infection Severe deformity of shoulder Any bleeding tendency disorders or use of anti coagulants Active rheumatologic disease Post stroke shoulder pain History of allergic reactions to the used drugs Pregnant or Lactating women Inability to communicate and completing questionnaires

**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**

The random allocation method in this study will be permutation block method in such a way that A represents the person for whom injection is done and B represents the person who receives oral Piroxicam. This method is based on blocks of six so that the total number of possible permutations of six is equal to 6 (including: ABAB, BABA, AABBB, BBAA, ABBA and BAAB). Then, by using the table of random numbers and assigning a code from 0 to 9 to each of the permutations, the desired random list of 60 items, which includes 15 blocks of 4 items (total number of samples = 60 x 15) is generated and the order of assigning each One of the methods is specified for each of the samples participating in the study.

**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 are aware of the type of intervention. Clinical caregiver: We train the person who is in charge of the care and follow-up of patients how to complete the questionnaire. This person has no awareness of the patient's intervention. Researcher: In this study, we do not have the ability to blind the researcher because the intervention is carried out by him. Outcome assessor: 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 improvement in each person according to the questionnaire. Data Analyzer: 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**

Shiraz university of medical science, Zand Ave

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Approval date**

2022-05-23, 1401/03/02

**Ethics committee reference number**

IR.SUMS.MED.REC.1401.094

**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 and two, four and eight weeks after intervention

#### Method of measurement

Visual Analog Scale and Oxford Shoulder Score questionnaires

### 2

#### Description

Range of motion of shoulder

#### Timepoint

Before intervention and two, four and eight weeks after intervention

#### Method of measurement

By goniometer, which is a device for measuring angles, the one that is used in this study is a plastic type with 360 degree rotation and an arm length of 30 cm.

## Secondary outcomes

### 1

#### Description

Function of patient

#### Timepoint

Before intervention and two, four and eight weeks after intervention

#### Method of measurement

Shoulder Pain And Disability Index and Oxford Shoulder Scale questionnaires

## Intervention groups

### 1

#### Description

Intervention group: At the Jianqian acupoint, which is between the axillary fold and the LI-15 acupoint (under the acromion), we inject a mixture of 40 mg of Methyl Prednisolone Acetate and 4 ml of Lidocaine2% in 5 directions in such a way that First, we insert the needle perpendicularly about 1.5 to 2 cm on the joint surface and outside the capsule and inject 1 cc of the substance, then without removing the needle, by changing the direction angle to 40 degrees to the vertical line , at upward ,downward and outside , we inject one cc on each side. At the inside, we enter at an angle of 10 degrees to the perpendicular line close to the joint capsule, and we are careful not to enter the pleura, and the injection is done. During the injection, we pay attention to the patient's reactions so as not to enter the blood vessels and nerves.

#### Category

Rehabilitation

### 2

#### Description

Control group: They take 10 mg Piroxicam capsules twice daily after meal and with enough water.

#### 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

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Shiraz

##### Province

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##### Phone

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##### Email

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### 2

#### Recruitment center

##### Name of recruitment center

Rajae hospital

##### Full name of responsible person

Amirreza Mesbahi

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##### Province

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7194815711

##### Phone

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##### Email

rajaeehospital@sums.ac.ir

## 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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Front of Maaref school, Khalili Ave

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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**  
 Lale Zare  
**Position**  
 Resident  
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 Medical doctor  
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 Physical Medicine  
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 No.3, 2nd Alley, Rayehe Ave, Golestan Town  
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## Person responsible for updating data

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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 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.lale zare dr.lalezare@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**