

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effect of Ketorolac sub acromial injection with methyl prednisolone in patient with shoulder impingement syndrome that refers to Isfahan university clinics in 2016-2017.

Protocol summary

Summary

This study is a single-blind randomized clinical trial on patients with shoulder impingement syndrome. Patient history, examination and shoulder X-ray (Ap & lat) will be produced. Before treatment, we use the VAS score for severity of pain and Constant Score for shoulder Range of motion and function in all patients. The patients randomly divide into two groups A and B (based on random number table). We mark site of injection on patient's skin in sitting position. After sterilization of injection site, physiatrist by posterior approach. inject 60 mg ketorolac (about 2 ml) with 1 ml of lidocaine in subacromial space (group A) and 1 ml of methyl prednisolone with 1 ml of lidocaine in subacromial space(group B).Then VAS and Constant Score measured again for each patient one and three months later and analysis with SPSS 20. In this study significant P-value is considered less than 0/05.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011231906N1**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

Sahar mousavi Ghahfarokhi

Name of organization / entity

Isfahan University of Medical Sciences, Physical

Medicine & Rehabilitation

Country

Iran (Islamic Republic of)

Phone

+98 913 300 2733

Email address

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Recruitment status

Recruitment complete

Funding source

Isfahan university of Medical Sciences

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Ketorolac sub acromial injection with methyl prednisolone in patient with shoulder impingement syndrome that refers to Isfahan university clinics in 2016-2017.

Public title

The effect of ketorolac in the treatment of shoulder impingement syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. age between 20 to 80 years old; 2. shoulder pain with the following positive test: the internal rotation resistance test (Neer test) and the Hawkins-Kennedy test; 3. approved participation in the

research project Exclusion criteria: 1. rheumatoid arthritis, osteoarthritis of the glenohumeral, complete tearing of the rotator cuff, shoulder girdle fracture, diabetes mellitus, infection and tumor; 2. change in treatment plan; 3. receiving subacromial injection from 8 weeks ago; 4. pregnant or plan to become pregnant; 5. there are risk factors for intra-articular injection, such as bleeding disorders or receiving anticoagulant; 6. contraindication for steroid injections / lidocaine and NSAID such as sensitivity to these drugs; 7. shoulder pain and dysfunction in the front side; 8. unavailability of patient after injection.

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of medical science.

Street address

Hezar jarib street. Isfahan University of medical science.

City

Isfahan

Postal code**Approval date**

2016-09-10, 1395/06/20

Ethics committee reference number

IR.MUI.REC.1395.3.596

Health conditions studied**1****Description of health condition studied**

Shoulder impingement syndrom

ICD-10 code

M75.4

ICD-10 code description

Impingement syndrome of shoulder

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

Pain

Timepoint

Admission, one and 3 months later

Method of measurement

Visual Analog Scale (VAS)

2**Description**

Function and range of motion

Timepoint

Admission, one and 3 months later

Method of measurement

Constant Shoulder Score

Secondary outcomes

empty

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

Patient history, examination and shoulder X-ray (Ap & lat) will be produced. Before treatment, we use the VAS score for severity of pain and Constant Score for shoulder Range of motion and function in group A. We mark site of injection on patient's skin in sitting position. After sterilization of injection site, physiatrist inject 2 ml of Ketorolac (60 mg) with 1 ml of lidocaine in subacromial space (group A) by posterior approach.

Category

Treatment - Drugs

2**Description**

Patient history, examination and shoulder X-ray (Ap & lat) will be produced. Before treatment, we use the VAS score for severity of pain and Constant Score for shoulder Range of motion and function in group B. We mark site of injection on patient's skin in sitting position. After sterilization of injection site, physiatrist inject 1 ml of methyl prednisolone with 1 ml of lidocaine in subacromial space (group B) by posterior approach.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr Sahar Mousavi

Street address

Sofe street

City

Isfahan

2

Recruitment center

Name of recruitment center

Ayat Allah Kashani hospital

Full name of responsible person

Dr Sahar Mousavi

Street address

Kashani street

City

Isfahan

3

Recruitment center

Name of recruitment center

Nour hospital

Full name of responsible person

Dr Sahar Mousavi

Street address

Ostandari street

City

Isfahan

4

Recruitment center

Name of recruitment center

Isa ebne Maryam hospital

Full name of responsible person

Dr Sahar Mousavi

Street address

Shams Abadi street

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Rasoul Rezayat

Street address

Isfahan University of Medical Sciences, Hezar jarib street.

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Sahar Mousavi

Position

MD

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Isfahan University of Medical Sciences

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Position

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Other areas of specialty/work**Street address**

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Postal code**Phone****Fax****Email**

s.mousavi.md@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