

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of therapeutic outcomes of intra-articular injection of Betamethasone and Methylprednisolone in frozen shoulder

Protocol summary

Study aim

Comparison of therapeutic outcomes of intra-articular injection of Betamethasone and Methylprednisolone in frozen shoulder

Design

RCT containing of 2 groups and 72 patients ,a double blind randomized study , random number table was used for randomized allocation

Settings and conduct

age sex duration of symptoms dominant hand comorbidities and smoking history are taken and registered .the patients are randomly divided into two equal groups (based on the table of random numbers). One group of patients is injected with 4 mg of betamethasone with 3 cc of 2% lidocaine and the other group is injected with 40 mg of methylprednisolone with 3 cc of 2% lidocaine. pain via VAS and shoulder ROM via goniometer are registered before injection and 1,3,6 months after injection. SPADI is registered before injection and 6months after injection.

Participants/Inclusion and exclusion criteria

inclusion criteria: patients with ages between 18 and 80 with clinical diagnosis of frozen shoulder including active and passive restriction of shoulder range of motion and written consent of participation in study with history of pain for 1 month at least and restriction of ROM for 3 months at least exclusion criteria: evidence of cuff full thickness tear or cuff partial thickness tear more than 50 % in MRI, evidence of Glenohumeral Osteoarthritis or calcium deposition in Xray, history of corticosteroid intraarticular injection in last 6 months or oral corticosteroid in last 2 weeks,history of fracture or surgery of shoulder joint , uncontrolled diabetes , neuromuscular diseases , evidence of bleeding susceptibility , shoulder septic arthritis or cellulitis

Intervention groups

a group of intra-articular injection of Betamethasone recipient and a group of intra-articular injection of Methylprednisolone recipient

Main outcome variables

pain via VAS (Visual Analog Scale) shoulder range of motion Shoulder Pain and Disability Index (SPADI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180423039388N1**

Registration date: **2024-04-21, 1403/02/02**

Registration timing: **registered_while_recruiting**

Last update: **2024-04-21, 1403/02/02**

Update count: **0**

Registration date

2024-04-21, 1403/02/02

Registrant information

Name

Amir Sobhanieraghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2264

Email address

Sobhani.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of therapeutic outcomes of intra-articular injection of Betamethasone and Methylprednisolone in frozen shoulder

Public title
Efficacy of Cortone injection on frozen shoulder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with ages between 18 and 80 active and passive restriction of shoulder range of motion (forward flexion less than 100 degrees, external rotation less than 30 degrees, internal rotation less than L1 vertebra, Stage 2 or 3 adhesive capsulitis according to the classification of Hannafin and Chiaia complaint of pain for 1month at least and of ROM restriction for 3 months at least written consent of participation in study
Exclusion criteria:
shoulder corticosteroids injection in last 6 months chronic long-term use of oral corticosteroids or in last 2 weeks history of shoulder surgery, shoulder fracture, shoulder dislocation in last 3 months shoulder septic or inflammatory arthritis or any evidence in favor of shoulder cellulitis uncontrolled Diabetes (HbA1C more than 7%, injection day BS more than 300) cuff full thickness tear or cuff partial thickness tear more than 50% in shoulder MRI Calcium deposition or Glenohumeral Osteoarthritis in shoulder AP and Axillary Xray neuromuscular diseases, systemic skeletal diseases, skeletal or soft tissue cancers of shoulder or organs around the shoulder use of Warfarin, Rivaroxaban, Apixaban, or any evidence in favor of bleeding susceptibility (INR>2, aptt>80 sec, platelet< 50000)

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
To perform randomization using a random numbers table , first, the researcher will determine the direction of reading the numbers in the table in advance (for example, up, down, left, or right), then use the default in considering the numbers for different groups. (for example, even numbers for intervention A and odd numbers for intervention B), the researcher will put his hand on one of the numbers, move in one of the

predetermined directions, record the numbers, and assign them to different groups. We will continue this work until the number of samples is complete.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, the double-blind (patients and researcher) will be used. That is, the outcome assessors and the participants will be unaware of the type of injected drug. Since the type of intervention is nameless and will be specified with special codes that cannot be distinguished, the patient and the outcome assessor can not be able to distinguish the type of intervention. On the other hand, the injection methods in the two methods are completely similar (such as similar equipment) and will be carried out in completely identical conditions so that patients cannot differentiate interventions.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Rasool Akram hospital, Mansoori street , Sattarkhan Blvd

City

Tehran

Province

Tehran

Postal code

1445613131

Approval date

2023-03-11, 1401/12/20

Ethics committee reference number

IR.IUMS.FMD.REC.1401.713

Health conditions studied

1

Description of health condition studied

frozen shoulder (adhesive capsulitis)

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

pain

Timepoint

before injection and 1, 3 , 6 months after injection

Method of measurement

visual analog scale

2

Description

shoulder range of motion

Timepoint

before injection and 1, 3 , 6 months after injection

Method of measurement

exam with goniometer

3

Description

shoulder and pain disability

Timepoint

before injection and 6 months after injection

Method of measurement

SPADI questionnaire(Shoulder Pain And Disability Index)

Secondary outcomes

empty

Intervention groups

1

Description

1st Intervention group: single dose of intra-articular injection of 1cc(40mg)Methylprednisolone mixed with 3cc lidocaine 2%

Category

Treatment - Drugs

2

Description

2nd Intervention group: single dose of intra-articular injection of 1cc(4mg)Betamethasone mixed with 3cc lidocaine 2%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Rasool Akram hospital

Full name of responsible person

Amir Sobhani Eraghi

Street address

Rasool Akram hospital , mansoori street , Sattarkhan Blvd

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1111

Fax**Email**

Rasoolhospital@iums.ac.ir

Web page address

<https://hrmc.iums.ac.ir/>

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

deputy of research - Iran university of medical science

Full name of responsible person

Dr.khooi

Street address

Iran University of Medical Science, next to Milad Tower, Hemmat Expy, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8860 2219

Email

PR@iums.ac.ir

Web page address

<https://iums.ac.ir>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

deputy of research - Iran university of medical science

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

Iran University of Medical Sciences

Full name of responsible person

Amir Sobhani Eraghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Rasool Akram hospital , mansoori street , Sattarkhan Blvd

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1111

Email

sobhani.a@iums.ac.ir

Web page address

<https://hrmc.iums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Amir Sobhani Eraghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Rasool Akram hospital , mansoori street , Sattarkhan Blvd

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1445613131

Phone

+98 21 6435 1111

Email

sobhani.a@iums.ac.ir

Web page address

<https://hrmc.iums.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Amir Sobhani Eraghi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Rasool Akram hospital , mansoori street , Sattarkhan Blvd

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available