Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 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 shoulde

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)

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+98 21 6435 2264

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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
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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
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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

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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