

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy and safety of US guided Intra-articular injections of Hyaluronic acid versus corticosteroid in patients with frozen shoulder (Adhesive Capsulitis)

Protocol summary

Study aim

Evaluation of efficacy and safety of intra-articular injection of hyaluronic acid and corticosteroid in treatment of frozen shoulder

Design

Randomized control trial with control parallel group, double blind

Settings and conduct

Subjects, interventionist, outcome assessor, statistician and the researcher are all blind to treatment groups allocation; using pre-filled syringes and sealed envelopes. Subjects will be randomly allocated in 2 groups of 20 (injection of hyaluronic acid with lidocaine or triamcinolone with lidocaine). The study will take place in Modarres hospital, Tehran.

Participants/Inclusion and exclusion criteria

Subjects with frozen shoulder symptoms; Exclusion criteria are any history of previous fracture, surgery, bone lesion in the affected shoulder; or physical therapy or intra-articular injections in the past 3 months; allergy to hyaluronic acid or steroids; recurrence of disease in the affected shoulder.

Intervention groups

US guided intra-articular injection of 1 cc hyaluronic acid with 1 cc lidocaine 2% US guided intra-articular injection of 1 cc triamcinolone 40 mg with 1 cc lidocaine 2%

Main outcome variables

Patient's pain severity and shoulder function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N28**

Registration date: **2019-08-01, 1398/05/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-01, 1398/05/10**

Update count: **0**

Registration date

2019-08-01, 1398/05/10

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

Email address

a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-22, 1398/04/31

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy and safety of US guided Intra-articular injections of Hyaluronic acid versus corticosteroid in patients with frozen shoulder (Adhesive Capsulitis)

Public title

Evaluation of hyaluronic acid effectiveness in treatment

of frozen shoulder

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 patients with frozen shoulder
Exclusion criteria:
 Recent fracture in the affected shoulder History of inflammation and joint infections Any bone lesion in the affected shoulder Physical therapy or any intra-articular injections in the glenohumeral joint during the past three months History of surgery on the affected shoulder History of allergy to steroids and hyaluronic acid Recurrence of the disease in the affected shoulder

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **40**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 Subjects with bilateral frozen shoulder will be randomly allocated to treatment groups.

Randomization (investigator's opinion)
Randomized

Randomization description
 In this study, subjects will be randomly allocated by individual simple randomization method to 2 intervention groups of 20, using computer random number generator, crating numbers between 0&1, and numbers smaller than 0.500 were allocated to group T1 (steroid) and numbers greater than 0.500 were allocated to group T2 (hyaluronic acid).

Blinding (investigator's opinion)
Double blinded

Blinding description
 Subjects will be blinded by using pre-filled syringes for injections, the interventionist is not in the research team. The researcher and the statistician are also blind to treatment groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethic Committe of Shahid Beheshti University of Medical Sciences
Street address
 No. 1983969411, Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran
City
 Tehran
Province
 Tehran
Postal code
 1983969411
Approval date
 2019-05-21, 1398/02/31
Ethics committee reference number
 IR.SBMU.MSP.REC.1398.215

Health conditions studied

1

Description of health condition studied
Frozen Shoulder
ICD-10 code
 M75.0
ICD-10 code description
 Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Pain
Timepoint
 Before intervention, 1 week and 4 weeks after injection.
Method of measurement
 Visual Analogue Scale

2

Description
Active and passive range of motion
Timepoint
 Before intervention, 1 week and 4 weeks after injection.
Method of measurement
 goniometer

3

Description
Shoulder function
Timepoint
 Before intervention, 1 week and 4 weeks after injection.
Method of measurement
 Oxford, Shoulder Pain and Disability Index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: US guided intra-articular injection of 1 cc hyaluronic acid with 1 cc lidocaine 2%

Category

Treatment - Drugs

2

Description

Control group: US-guided intra-articular injection of 1 cc triamcinolone 40 mg with 1 cc lidocaine 2%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Khadijeh Samadnejad

Street address

No 1998734383, Shahid Modarres hospital , Kaj Square, Sa'adat abad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

Street address

Shahid Modarres Hospital, Kaj square, Saadat abad

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Email

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khadijeh Samadnejad

Position

Resident in Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Seyed Ahmad Raeissadat

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Resident in Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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