Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
kh.samadnejad@gmail.com

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
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
a_raeissadat@sbmu.ac.ir
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
Shahid Modarres Hospital, Kaj square, Saadat abad
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
kh.samadnejad@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ahmad Raeissadat
Position
Associate Professor
Latest degree
Specialist

Other areas of specialty/work
Physical Medicine
Street address
Shahid Modarres Hospital, Kaj square, Saadat abad
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
a_raeissadat@sbmu.ac.ir

Person responsible for updating data

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
No. 1998734383, Shahid Modarres Hospital, Kaj square, Saadat abad
City
Tehran
Province
Tehran
Postal code
1998734383
Phone
+98 21 2236 3244
Email
kh.samadnejad@gmail.com

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