Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of ultrasound guided injection of hyaluronic acid, hyaluronidase enzyme and triamcinolone in the treatment of frozen shoulder

Protocol summary

Study aim

The aim of this study is comparing of the effectiveness of intra-articular injections of hyaluronic acid, hyalase and corticosteroids in reducing pain, improving function, shoulder range of motion, and the level of treatment's satisfaction in patients with frozen shoulder.

Design

A controlled, parallel-group, double blind, randomized, phase 3 clinical trial on 90 patients. Random allocation software is used for randomization.

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 3 groups. The study will take place in Modarres hospital, Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: people aged 25 to 70 years who have been diagnosed with adhesive capsulitis and have not responded to conservative treatments and have scored 5 or higher based on pain intensity scale (VAS) and less than 6 months from the onset of symptoms .Exclusion criteria : History of shoulder trauma in the last 6 months; history of humerus fracture or tearing of rotator cuff muscles; pregnancy and breastfeeding; history of shoulder surgery and inflammatory systemic diseases

Intervention groups

Intervention group1: includes 30 patients who are treated with Hyalase injection, 1500 units in 5 cc of normal saline along with 2 cc of 2% lidocaine. Intervention group 2: includes 30 patients who are treated with 2.5 cc of hyaluronic acid with 2.5 cc of normal saline and 2 cc of lidocaine. Control group: includes 30 patients who are treated with injection of 40 mg of triamcinolone along with 4 cc of normal saline and 2 cc of 2% lidocaine.

Main outcome variables

Active range of motion of shoulder, assessment of shoulder pain, assessment of patient's performance in daily tasks and degree of patient's satisfaction.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N32**
Registration date: **2023-09-13, 1402/06/22**
Registration timing: **prospective**

Last update: **2023-09-13, 1402/06/22**
Update count: **0**

Registration date

2023-09-13, 1402/06/22

Registrant information

Name
Seyed Ahmad Raeissadat
Name of organization / entity
Modares Hospital
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ultrasound guided injection of hyaluronic acid, hyaluronidase enzyme and triamcinolone in the treatment of frozen shoulder

Public title

Comparison of ultrasound guided injection of hyaluronic acid, hyaluronidase enzyme and triamcinolone in the treatment of frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People aged 25 to 70 years have been diagnosed with adhesive capsulitis based on history and physical examination and did not respond to conservative treatments including non-steroidal pain relievers, exercise therapy and physical modalities. According to VAS criteria, they have scored 5 or higher. More than 30 degrees restriction of shoulder active range of motion in at least 2 of 4 directions of motion (abduction, flexion, external rotation and internal rotation) compared to the range of motion of the healthy shoulder (opposite side). Less than 6 months have passed since the onset of symptoms.

Exclusion criteria:

History of shoulder trauma in the last 6 months History of humerus bone fracture, supraspinatus tear, subacromial bursitis, calcific tendonitis and acromioclavicular joint osteoarthritis Pregnancy and breastfeeding. The presence of nerve injury or the presence of neurological disorders that cause dysfunction of the upper limbs, including brachial plexus plexopathy, hemiplegia and peripheral nerve injury Known allergy or sensitivity to hyalase, hyaluronic acid, or corticosteroids Psychological problems History of shoulder surgery A patient who is unable to cooperate to check the range of motion due to severe pain History of shoulder intra-articular injection of corticosteroids and hyaluronic acid in the last 6 months Inflammatory systemic diseases, hypothyroidism, hyperthyroidism and diabetes Use of anticoagulants

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial study, 90 patients diagnosed with frozen shoulder will be randomly enrolled. Block randomization method will be used for random allocation of people in the studied groups. In this method, blocks of 9 will be used with a ratio of 1:1:1. Random Allocation software will be used to generate random sequences. For concealment, random allocation concealment method will be used, which is marked with the letters A (Hyalase receiving group), B (Triamcinolone receiving group) and C (Hyaluronic acid receiving group) and recorded on cards. These cards will be placed in the sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then based on The order of entry of the eligible participants, the envelopes will be opened and the assigned group of that participant will be known.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher, patients and the collaborator of the project who will perform the statistical analysis will not be aware of the study . grouping of patients will be noted and will be shared to one of the partners

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-08-09, 1402/05/18

Ethics committee reference number

IR.SBMU.LASER.REC.1402.017

Health conditions studied

1

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

Primary outcomes

1

Description
Active range of motion of shoulder
Timepoint
At the beginning of the study (before intervention) and 8 weeks and 24 weeks after the intervention
Method of measurement
Digital goniometer

2

Description
Assessment of shoulder pain
Timepoint
At the beginning of the study (before intervention) and 8 weeks and 24 weeks after the intervention
Method of measurement
Visual analogue scale (VAS)

3

Description
Assessment of the patient's performance in daily tasks
Timepoint
At the beginning of the study (before intervention) and 8 weeks and 24 weeks after the intervention
Method of measurement
Oxford Shoulder Score (OSS)

Secondary outcomes

1

Description
The degree of patient's satisfaction with the treatment
Timepoint
At the beginning of the study (before intervention) and 8 weeks and 24 weeks after the intervention
Method of measurement
5-items questionnaire

Intervention groups

1

Description
Intervention group: Includes 30 patients who are treated with hyalase injection at the rate of 1500 units in 5 cc of normal saline along with 2 cc of 2% lidocaine.
Category
Treatment - Drugs

2

Description
Intervention group: Includes 30 patients who are treated with triamcinolone injection in the amount of 40 mg (one cc) along with 4 cc of normal saline and 2 cc of 2% lidocaine.
Category
Treatment - Drugs

3

Description
Intervention group: Including 30 patients who are treated with 2.5 cc of hyaluronic acid (20 mg per cc) along with 2.5 cc of normal saline and 2 cc of lidocaine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modarres hospital
Full name of responsible person
Seyed Ahmad Raeissadat
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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Laser Research Center, 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
Ali Nazari Nodoushan
Position
Resident of Physical medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document

All the data of people participating in this study can be shared after deidentifying people

When the data will become available and for how long

The access period starts one year after the results are published

To whom data/document is available

Data of this study will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

If the goal of the researchers is to conduct a systematic review and meta-analysis on the data, the non-identifiable data of the patients will be provided to the researchers.

From where data/document is obtainable

By sending an email to alin7093@gmail.com

What processes are involved for a request to access data/document

Sending an e-mail and explaining the purpose and how to use the data

Comments