

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of ultrasound-guided corticosteroid and botulinum toxin in frozen shoulder

Protocol summary

Study aim

The purpose of this study is to evaluate the effectiveness of intra-articular injection of botulinum toxin in reducing pain, improving function and range of motion of the shoulder compared to intra-articular injection of corticosteroids in patients with frozen shoulder.

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 60 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 2 groups of 30 (injection of botulinum toxin with lidocaine or triamcinolone with lidocaine). The study will take place in Modarres hospital, Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria : People aged 30 to 60 years who have been diagnosed with adhesive capsulitis and did not respond to conservative treatments and based on VAS criteria, it should have a score of 5 or higher and 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 fracture; pregnancy and breastfeeding; allergy to botulinum toxin or corticosteroids.; presence of psychological problems; history of shoulder surgery; any intra-articular injection in the involved shoulder within the last 6 months and inflammatory systemic diseases

Intervention groups

Intervention group: Includes 30 patients who are treated with 200 units of botulinum toxin (Masport, Masson Darou) and 1 cc of lidocaine intra-articularly. Control group: Includes 30 patients who are treated with triamcinolone (40 mg intra-articular) with 1 cc of lidocaine.

Main outcome variables

Active range of motion of shoulder, Assessment of shoulder pain, Assessment of the patient's performance in daily tasks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N31**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2023-06-10, 1402/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ultrasound-guided corticosteroid and botulinum toxin in frozen shoulder

Public title

Comparison of ultrasound-guided corticosteroid and botulinum toxin in frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People aged 30 to 60 years Diagnosed with adhesive capsulitis based on history and physical examination No response to conservative treatments, including non-steroidal anti-inflammatory drugs, opioids, exercise therapy, and physical therapy. A score of 5 or higher based on the intensity of the pain (according to the VAS criteria) Less than 6 months have passed since the onset of the symptoms Have more than 30 degree reduction in the range of motion in at least 2 of the 4 directions of motion (abduction, flexion, external rotation, and internal rotation) compared to the range of motion of the healthy shoulder (opposite side)

Exclusion criteria:

History of shoulder trauma in the last 6 months History of humerus fracture Pregnancy and breastfeeding The presence of nerve damage or neurological disorders that cause dysfunction of the upper limbs, including brachial plexopathy, hemiplegia, and peripheral nerve damage. Allergy or known sensitivity to botulinum toxin or corticosteroids Presence of 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 intra-articular injection in the last 6 months Inflammatory systemic diseases Use of anticoagulants The presence of diseases that involve the connection between nerve and muscle, such as myasthenia gravis and Eaton Lambert

AgeFrom **30 years** old to **60 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

in this clinical trial study, 60 patients with a diagnosis of frozen shoulder will be included in the study randomly

.For random allocation of individuals in the study groups (intervention or intervention group and comparison or comparison group), the method of random allocation with block method (Block Randomization) will be used In this method, blocks with size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1: 1 will be used. Random Allocation software will be used to generate random sequences. For concealment, the random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified with two type of cards which are including group a (intervention group) and b (comparison group) and these cards are placed inside 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, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined.

Blinding (investigator's opinion)

Triple 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

Parallel

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

2022-07-24, 1401/05/02

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.266

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 6 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 6 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 6 weeks and 24 weeks after the intervention

Method of measurement

Oxford Shoulder Score (OSS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Includes 30 patients who are treated with 200 units of botulinum toxin (Masport, Masson Darou) and 1 cc of lidocaine intra-articularly.

Category

Treatment - Drugs

2

Description

Control group: Includes 30 patients who are treated with

triamcinolone (40 mg) with 1 cc of lidocaine (2%) intra-articularly.

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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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

Seyed Ahmad Raeissadat

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Grant name

H-index between 10 and 15 in Scopus

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti 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**

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

Physical Medicine

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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

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

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resident of 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)**

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

No - There is not 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 ali.nazari32@yahoo.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