Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of three methods of injection under ultrasound guidance inside the shoulder joint and hydrodistension of the shoulder joint and suprascapular nerve block on shoulder function in patients with frozen shoulder.

Protocol summary

Study aim

Determining and comparing the effectiveness of three methods: 1) suprascapular block injection with 2) methylprednisolone injection with 3) hydrodistension injection, in reducing pain and improving shoulder function and sleep quality of patients.

Design

Our study is a clinical trial without a control group, which is randomized in 3 parallel groups, three blind, and phase 3 is a clinical trial that is conducted on 102 patients. For randomization, block random division produced by Random Allocation Software was used in blocks of six into three groups with a ratio of 1:1:1.

Settings and conduct

Patients after randomization, in room number 9 of the operating room by an anesthesiologist under ultrasound guidance and with a gray spine needle injection of the shoulder in one of three types: 1) suprascapular nerve block and 2) methylprednisolone and 3) hydrodistension of the shoulder joint based on the internal group The envelope is done. In this study, both the patients, the outcome assessor, and the data analyst are blinded. In order to hide the random allocation, the codes created by the software will be placed in non-transparent and sealed envelopes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-60 years Definitive diagnosis of frozen shoulder Failure to respond to non-invasive treatments exclusion criteria: History of recent trauma or surgery Acromioclavicular joint osteoarthritis radiculopathy

Intervention groups

1) Intra-articular injection of the shoulder under ultrasound guidance 2) Suprascapular notch injection under ultrasound guidance 3) Intra-articular hydrodeposition injection under ultrasound guidance

Main outcome variables

Shoulder function, sleep quality

General information

Reason for update

To examine the amount of shoulder movement and ROM, we had defined it with only one variable in the protocol, but during the examination with the goniometer, each movement had to be measured separately and entered into the questionnaire. We separated the 4 basic movements of the shoulder, which include abduction and flexion, sternal rotation and internal rotation, and included each as a separate variable in the protocol. We also added another variable called recovery time, which examines the time the patient reached recovery in the 3 groups so that a better comparison can be made between the groups, which is based on the criteria of pain and ROM.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230316057742N2**
Registration date: **2024-04-30, 1403/02/11**
Registration timing: **prospective**

Last update: **2025-07-25, 1404/05/03**
Update count: **2**

Registration date

2024-04-30, 1403/02/11

Registrant information

Name

majid khalilizad

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-21, 1403/03/01

Expected recruitment end date

2025-05-22, 1404/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of three methods of injection under ultrasound guidance inside the shoulder joint and hydrodistension of the shoulder joint and suprascapular nerve block on shoulder function in patients with frozen shoulder.

Public title

Investigation of three injection methods under ultrasound guidance inside the shoulder joint in patients with frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of ice shoulder by an orthopedic doctor Failure to respond to non-invasive treatments such as physiotherapy and drug therapy Active and passive reduction of rom movements Age between 18-60 years

Exclusion criteria:

known systemic diseases such as rheumatoid arthritis History of recent trauma or surgery or known chronic disease (such as rotator cuff lesions) Pivacaine, any known systemic disease Midclavicular joint, cervical radiculopathy Brachial plexopathy, neoplasm pregnancy Addiction to opioids diabetes Osteoarthritis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, the data analyst and the result evaluator and the participant are blinded. Due to the same treatment method (injection) and the same color of injectable drugs and the same injection site in all three groups, the possibility of blinding at the participant level is also possible.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Shahid Beheshti Hospital, Shahid Sargerd Ghasemi St , Babol

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babol

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Postal code

4716681451

Approval date

2024-03-06, 1402/12/16

Ethics committee reference number

IR.MUBABOL.REC.1402.232

Health conditions studied

1

Description of health condition studied

Adhesive capsulitis of shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Score obtained on the Shoulder Pain and Disability Index

Timepoint

Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention

Method of measurement

Shoulder Pain and Disability Index

2

Description
Score obtained on the Pittsburgh Sleep Quality Questionnaire
Timepoint
Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention
Method of measurement
Pittsburgh Sleep Quality Index

3

Description
Visual Analogue Pain Scale
Timepoint
Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention
Method of measurement
Score obtained on the visual analog scale

4

Description
Shoulder Internal Rotation Movement Scale score
Timepoint
Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention
Method of measurement
Score obtained based on the goniometer device

5

Description
Shoulder external rotation movement scale score
Timepoint
Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention
Method of measurement
Score obtained based on the goniometer device

6

Description
Shoulder abduction range of motion score
Timepoint
Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention
Method of measurement
Score obtained based on the goniometer device

7

Description
Shoulder flexion movement scale
Timepoint
Before the injection and during the follow-up times 2-6-12-24 weeks after the intervention
Method of measurement
Score obtained based on the goniometer device

8

Description
Time to recovery
Timepoint
At follow-up times every week after the intervention
Method of measurement
Recovery of maximum shoulder ROM based on goniometry and absence of pain based on visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
After the diagnosis of frozen shoulder by the orthopedist in the clinic, the patients refer to the operating room for injection and are randomly divided into three groups. For injection, a gray spine needle number 27 is used. The exact location of the injection is determined using an ultrasound guide, and the desired drugs are 2% lidocaine ampoule from Caspin Tamin Company, 40 mg methylprednisolone acetate ampoule from Elixir Company, and distilled water from Shahid Ghazi Company. Only one injection is given to the patients and then they undergo follow-up for 24 weeks, which will include 5 examinations. Once upon entering the clinic, then 2 weeks after the injection, 6 weeks after the injection, 12 weeks after the injection, and 24 weeks after the injection, the patients are examined. Group A, in which the injection under ultrasound guidance inside the shoulder joint in the form of hydrodistention, which includes (5 cc of distilled water, 5 cc of 2% lidocaine hydrochloride) will be injected into the patient's shoulder.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group B: intra-articular injection (5 cc lidocaine hydrochloride 2% + 1 cc methylprednisolone 40 mg + 4 cc distilled water)
Category
Treatment - Drugs

3

Description
Intervention group: Intervention group C: Suprascapular nerve block (2 cc lidocaine hydrochloride 2% + 1 cc prednisolone 40 mg + 2 cc distilled water)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid beheshti hospital

Full name of responsible person
Majid Khalilizad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Babol 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
Babol University of Medical Sciences

Full name of responsible person
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Position
Senior Orthopedic Resident

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The time of data release is one year after the results are published
To whom data/document is available
The data will be available only to researchers working in academic and scientific institutions and orthopedic specialist colleagues
Under which criteria data/document could be used
Other than the above conditions, there is no specific limitation in the data
From where data/document is obtainable
To Dr. Khalilzad, knee specialist, faculty of Babol University of Medical Sciences 09143822836
What processes are involved for a request to access data/document
majidkhalizad@yahoo.com Dr. Khalilzad, orthopedic specialist
Comments