

# 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 khalilzad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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**Email address**

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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

**City**

babol

**Province**

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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**

## 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**

Babol University of Medical Sciences

**Full name of responsible person**

Mahdi Rajabnia

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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**

yasin sharifzadeh

**Position**

Senior Orthopedic Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

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**Position**

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**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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yasin sharifzadeh

**Position**

Senior Orthopedic Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

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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**