

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 2026

### The short-term Effect of Physiotherapy in comparison to Intraarticular Corticosteroid Injection on Pain, Disability, and Effectiveness of Treatment in Patients with Frozen Shoulder: Randomized Controlled Trial

#### Protocol summary

##### Study aim

The purpose of this study was to compare the short-term effect of Physiotherapy and Intraarticular Corticosteroid Injection on Pain, Disability and effectiveness of Treatment in patients with Frozen shoulder.

##### Design

This clinical trial is a randomized, superiority, parallel, blinded, multicenter study with 48 participants in two groups (24 in each group).

##### Settings and conduct

After the initial evaluation via the blinded assessor and randomization at Orthopedics clinic of Prof. Mohammad Hossein Ebrahim Zade, Physiotherapy group will receive the treatment at Special Physiotherapy clinic of Qaem Hospital. The injection group will receive the treatment at Orthopedics clinic of Prof. Mohammad Hossein Ebrahim Zade.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years, Abduction and External rotation limitation (More than 50% of normal range), A minimum history of 4 weeks of Shoulder pain, Absence of coagulative diseases, Sleep disturbances due to pain and incapability of sleeping on the affected side. Exclusion criteria: History of severe trauma to the shoulder, History of neck radiculopathy, History of complete Rotator Cuff tear, Severe infection, History of Glenohumeral joint fracture, Presence of malignancy in Shoulder 4 to 6 months after Radiotherapy in Shoulder, Injection contraindications (Allergic to Drug, etc.)

##### Intervention groups

Comprehensive physiotherapy with hot pack application, low level laser therapy, glenohumeral joint mobilizations and Proprioceptive neuromuscular facilitation techniques. Intra-articular Corticosteroid injection into the glenohumeral joint via the posterior approach.

##### Main outcome variables

Pain via the Visual Analogue Scale (VAS) and Shoulder Pain and Disability Index (SPADI); Disability via SPADI; The effectiveness of treatment via the Global Rate of Change (GRC) scale.

#### General information

##### Reason for update

Procedural Change (Drug dosage), Allocation and randomization location change, minor changes and clarification in execution.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161221031506N8**

Registration date: **2022-03-21, 1401/01/01**

Registration timing: **prospective**

Last update: **2022-12-24, 1401/10/03**

Update count: **1**

##### Registration date

2022-03-21, 1401/01/01

##### Registrant information

##### Name

Salman Nazary-Moghadam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3884 6713

##### Email address

nazaryms@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-04, 1401/01/15

**Expected recruitment end date**

2023-03-16, 1401/12/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The short-term Effect of Physiotherapy in comparison to Intraarticular Corticosteroid Injection on Pain, Disability, and Effectiveness of Treatment in Patients with Frozen Shoulder: Randomized Controlled Trial

**Public title**

Comparison of Drug Injection and Physiotherapy in patients diagnosed with Frozen Shoulder

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients older than 18 years Abduction and External rotation limitation (More than 50% of normal range) A minimum history of 4 weeks of Shoulder pain Absence of coagulative diseases Sleep disturbances due to pain and incapability of sleeping on the affected side

**Exclusion criteria:**

History of severe trauma to the shoulder History of neck radiculopathy History of complete Rotator Cuff tear Severe infection History of Glenohumeral joint fracture Presence of malignancy in Shoulder 4 to 6 months after Radiotherapy in Shoulder Injection contraindications (Allergic to Drug, etc.)

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyst

**Sample size**

Target sample size: **48**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using stratified randomization, two indexes of numbers 1 and 2, which belong to physiotherapy (number 1) and injection (number 2), respectively, will be generated from "sealedenvelope.com" and put into opaque, sealed envelopes. one group of envelopes belongs to diabetic patients and the other group, to non-diabetic patients. Based on the mean and standard deviation of the SPADI questionnaire score in similar Studies, while considering a 10% drop rate, 24 subjects will be allocated to each group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants will choose from sealed, opaque envelopes. Another physiotherapist who is not aware of the allocation will evaluate the patients in a separate room. Data analyst will be blinded when performing statistical analysis using codes A and B for intervention groups in the statistical analysis software.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

The Ethics Committee of Mashhad University of Medical Sciences

**Street address**

Mashhad University of Medical Science's Research and Development Deputy Office, Across 18th University Street, University Street.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2022-02-26, 1400/12/07

**Ethics committee reference number**

IR.MUMS.REC.1400.345

**Health conditions studied****1****Description of health condition studied**

Adhesive capsulitis of shoulder (Frozen Shoulder)

**ICD-10 code**

M75.0

**ICD-10 code description**

Adhesive capsulitis of shoulder

**Primary outcomes****1****Description**

Pain

**Timepoint**

Immediately After Allocation, 6 weeks after Randomization

**Method of measurement**

Shoulder Pain and Disability Index (SPADI) questionnaire,

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Disability

#### Timepoint

Immediately After Allocation, 6 weeks after Randomization

#### Method of measurement

Shoulder Pain and Disability Index (SPADI) questionnaire

### 2

#### Description

The Effectiveness of Treatment

#### Timepoint

6 weeks after randomization

#### Method of measurement

Global Rating of Change Scale

## Intervention groups

### 1

#### Description

Intervention group: In physiotherapy group, who will receive 10 sessions, 3 sessions weekly, after hot pack application for 15 minutes, low level laser with 1.8 joules of energy per point will be applied for 30 seconds on 8 painful points of the glenohumeral capsule. Afterwards, a grade 2 glenohumeral mobilization for improving Abduction and External Rotation will be applied. Finally, the D2 flexion pattern of the involved extremity accompanied by Hold Relax technique, performed with 10 seconds of antagonist muscle contraction, will be applied 5 times per each session.

#### Category

Rehabilitation

### 2

#### Description

Control group: 40 milligrams of Triamcinolone (1 Milliliter) and 9 Millilitres of 2 percent Lidocaine, will be injected into glenohumeral joint via posterior approach

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physical Therapy Clinic of Qaem Hospital

##### Full name of responsible person

Mr. Javad Zarandi

##### Street address

Narjes building, first floor, Physiotherapy Department,

Qaem Hospital, Nurse Street.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9176699199

##### Phone

+98 51 3841 1538

##### Email

zarandiMJ1@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Majid Ghayour Mobarhan

##### Street address

Ghoreshi Building, Doctora Crossroad.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9919191778

##### Phone

+98 51 3841 1538

##### Email

vcresearch@mums.ac.ir

#### Grant name

Personal Grant (Dr. Salman Nazary-Moghadam)

#### Grant code / Reference number

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

Yes

#### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohammad Ali Zare

##### Position

MSc Colleague

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Faculty of Paramedical Sciences, University campus,  
East entrance of Ferdowsi University of Mashhad,  
Azadi Square, Mashhad.

**City**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

MSc Colleague

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Bachelor

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## Person responsible for updating data

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Mashhad University of Medical Sciences

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Mohammad Ali Zare

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## 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**

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**

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 data will be reported in the form of a research article.  
Raw data will be delivered to researchers for meta analysis.

**When the data will become available and for how long**

6 months after publication

**To whom data/document is available**

For researchers only.

**Under which criteria data/document could be used**

For meta-analysis Only.

**From where data/document is obtainable**

mohammadalizare6@gmail.com

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

The response will be sent 3 within months after considering the researcher's request.

**Comments**