

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of joint mobilization and proprioceptive neuromuscular facilitation (PNF) on pain, range of motion and function of the patients with shoulder adhesive capsulitis; a randomized clinical trial

#### Protocol summary

##### Study aim

To determine the additional effect of combined joint mobilization and PNF on pain, function, and range of motion in patients with shoulder adhesive capsulitis

##### Design

Randomized, superiority, parallel-group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site

##### Settings and conduct

Sports medicine clinic of Imam khomeini hospital

##### Participants/Inclusion and exclusion criteria

Inclusion: Age between 40 & 70; Diagnosed unilateral shoulder adhesive capsulitis, as pain, stiffness and limitation of passive movement compared with the opposite side; More than 3 months after the start of symptoms. Exclusion: Other pathologic conditions in shoulder or neck; Severe trauma or fracture; Infection; Pregnancy; Cardiologic, psychiatric, and any other severe diseases impairing the active participation in the study; Any type of manual therapies or intraarticular injections in the course of disease before inclusion in study.

##### Intervention groups

Intervention group: Intraarticular corticosteroid injection + general exercises + 5 sessions of joint mobilization and PNF Control group: Intraarticular corticosteroid injection + general exercises

##### Main outcome variables

Pain Function Range of motion in flexion, external rotation, abduction, and internal rotation

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111116008117N5**

Registration date: **2021-12-22, 1400/10/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-22, 1400/10/01**

Update count: **0**

##### Registration date

2021-12-22, 1400/10/01

##### Registrant information

###### Name

Farzin Halabchi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2282

###### Email address

fhalabchi@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-22, 1400/10/01

##### Expected recruitment end date

2022-08-23, 1401/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of joint mobilization and proprioceptive neuromuscular facilitation (PNF) on pain, range of motion and function of the patients with

shoulder adhesive capsulitis; a randomized clinical trial

### Public title

Investigating the effect of joint mobilization and PNF on shoulder adhesive capsulitis

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age between 40 & 70 Diagnosed unilateral shoulder adhesive capsulitis (idiopathic or diabetes-related) as pain, stiffness and more than 50% limitation of passive movement in one or more movements of external rotation, abduction and internal rotation compared with the opposite side More than 3 months after start of symptoms

#### Exclusion criteria:

Other pathologic conditions in shoulder or neck Severe trauma or fracture Infection Pregnancy Cardiologic, psychiatric, and any other severe diseases impairing the active participation in the study Any type of manual therapies or intraarticular injections in the course of disease before inclusion in study

### Age

From **40 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization in sizes of 2, 4 and 6 Randomization unit: Individual Randomization tool: Random digits tables The researcher who will assess the outcomes is not aware of the patient allocation.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

Because the interventions are performed as manual therapies and special exercises, blinding of the participants and care provider is not possible, but the outcome assessors and data analyzers will be blind to the allocation of participants to intervention or control groups.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research ethics committee of Imam Khomeini Hospital Complex,, Tehran University of Medical Sciences

##### Street address

Department Sports and Exercise Medicine, Imam Khomeini Hospital, Keshavarz Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1419733141

#### Approval date

2021-12-01, 1400/09/10

#### Ethics committee reference number

IR.TUMS.IKHC.REC.1400.362

## 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

Pain

#### Timepoint

before & immediately after intervention period

#### Method of measurement

VAS score

### 2

#### Description

Function

#### Timepoint

before & immediately after intervention period

#### Method of measurement

SPADI (Shoulder Pain And Disability Index) score: A 13 items questionnaire to assess function and disability of shoulder with reported good validity and reliability.

## Secondary outcomes

### 1

#### Description

Range of motion - abduction

**Timepoint**

Before and immediately after intervention

**Method of measurement**

Goniometric measurement

**Intervention groups**

**1**

**Description**

Intervention group: Joint mobilization (5X20minutes joint mobilization sessions including PNF D1 & D2 patterns)+ usual care (Intraarticular corticosteroid injection plus home exercises)

**Category**

Rehabilitation

**2**

**Description**

Control group: Usual care (Intraarticular corticosteroid injection plus home exercises)

**Category**

Rehabilitation

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Sports medicine clinic, Imam Khomeini hospital, Tehran university of medical sciences

**Full name of responsible person**

Farzin Halabchi

**Street address**

Keshavarz Blvd.

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fhalabchi@tums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Akbar Fotoohi, Vice Chancellor of research Tehran University of Medical Sciences

**Street address**

Imam Khomeini Hospital, Keshavarz Blvd.

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**Grant name**

Vice Chancellor of research - Tehran University of Medical Sciences

**Grant code / Reference number**

1400-2-101-54488

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Farzin Halabchi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**Web page address**

## 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 collected deidentified data

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

12 months after publication

**To whom data/document is available**

Only for people working in academic institutions

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

No specific criteria

**From where data/document is obtainable**

email of the corresponding person fhalabchi@tums.ac.ir

clinic contact phone: +982161192282

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

All de-identified data will be provided 1 month after request.

**Comments**