

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### : Effects of Acromioclavicular joint mobilization on symptoms and functional disability in patients with Frozen Shoulder Syndrome: A randomized controlled trial

#### Protocol summary

##### Study aim

Determination of acromioclavicular joint mobilization effects on symptoms and function of patients with frozen shoulder.

##### Design

A single blinded randomized controlled clinical trial of 56 patient with frozen shoulder.

##### Settings and conduct

Target population are all people who presenting with frozen shoulder at specialized physical medicine and rehabilitation clinics of Tabriz university of medical sciences . They will be enrolled in the study if they have included criteria and have not excluded criteria. The patients will divide randomly into 2 groups (A,B) by computerized randomization with Excel software.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 to 60 years Unilateral frozen shoulder Normal shoulder Xray and normal neurological examination At least two months passing from the onset of symptoms : exclusion criteria: Inflammatory or infectious shoulder joint disease Poor controlled diabetes Neoplastic disorder of shoulder region A recent history of fracture, dislocation ,subluxation ,steroid injection or surgery of shoulder complex

##### Intervention groups

In experimental group, Acromioclavicular joint mobilization techniques will be performed in the form of passive accessory inferior ,posterior to anterior & anterior to posterior glides( grade 3 &4) up to 6 sessions they also will receive physiotherapy and exercise such as control group. control group will receive 10 sessions of shoulder physiotherapy three times a week with range of motion,stretching and isometric strengthening exercises of shoulder muscles at home twice a day for twenty days

##### Main outcome variables

Shoulder range of motion Functional disability Pain severity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100605004104N7**

Registration date: **2019-01-06, 1397/10/16**

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

Last update: **2019-01-06, 1397/10/16**

Update count: **0**

##### Registration date

2019-01-06, 1397/10/16

##### Registrant information

##### Name

Mohammad Rahbar

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1544 6694

##### Email address

rahbarm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2020-03-20, 1399/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

: Effects of Acromioclavicular joint mobilization on symptoms and functional disability in patients with Frozen Shoulder Syndrome: A randomized controlled trial

**Public title**

Effects of Acromioclavicular joint mobilization in Frozen Shoulder Syndrome

**Purpose**

Treatment

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

Age between 18 to 60 years Unilateral frozen shoulder Normal shoulder Xray and normal neurological examination At least two months passing from the onset of symptoms

**Exclusion criteria:**

Inflammatory or infectious shoulder joint disease Neurological deficit such as stroke which is due to shoulder muscle dysfunction Poor controlled diabetes Neoplastic disorder of shoulder region A recent history of fracture, dislocation or subluxation of shoulder complex A history of steroid injection of glenohumeral joint, subdeltoid burse or acromiocalvicular joint within the previous 6 months or surgery A feeling of instability at the glenohumeral joint Shoulder pain referred from the severe cervical radiculopathy.

**Age**From **18 years** old to **60 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**Target sample size: **56****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will divide randomly into 2 groups (A,B) by computerized randomization with Excel software and this sequence will be written in separate envelopes and then will be placed in a box. The patients will treat with sequence of this box.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

For concealment of allocation and we will write sequence (A,B) based on computerized randomization in separate pockets and will be placed in a box. The patients will treat with sequence of this box. No researcher and statistical analyst will be aware of the type of intervention received.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethic committee of Tabriz University of Medicine

**Street address**

Golgasht Street, Central Department no.2, Vice Chancellor for Research, Tabriz University of Medical Sciences

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614756

**Approval date**

2018-11-19, 1397/08/28

**Ethics committee reference number**

IR.TBZMED.REC.1397.671

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

Frozen shoulder

**ICD-10 code**

M75.0

**ICD-10 code description**

Adhesive capsulitis of shoulder

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

Ability to manage in everyday life

**Timepoint**

before treatment, immediately after treatment.

**Method of measurement**

Shoulder Pain and Disability Index Questionnaire

**2****Description**

Range of motion of shoulder joints

**Timepoint**

before treatment and immediately after treatment.

**Method of measurement**

Goniometer

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#### **Description**

Pain severity

#### **Timepoint**

Before treatment, immediately after treatment

#### **Method of measurement**

Visual Analogue Scale with grading from zero to 10 centimeters.

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Acromioclavicular joint mobilization techniques will be performed in the form of passive accessory inferior ,posterior to anterior & anterior to posterior glides( grade 3 &4) ,of the distal end of the clavicle in physiological position for up to 6 sessions in the course of therapy by one expert therapist. patients also will receive physiotherapy and exercise such as control group.

#### **Category**

Treatment - Other

#### 2

#### **Description**

Control group: They will receive 10 sessions of shoulder physiotherapy three times a week with range of motion,stretching and isometric strengthening exercises of shoulder muscles at home twice a day for twenty days that will be conducted in a pain free manner. physiotherapy includes: hot pack for 20 minutes with heat of 74.5 degrees Celsius. Electrical nerve stimulation with frequencies of 70 to 80 hertz for 25 minutes. Continuous ultrasonography with dose of 1.25 to 1.5 w/cm2, and range of motion and stretching exercise .

#### **Category**

Rehabilitation

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Imam Reza University Hospital

##### **Full name of responsible person**

Dr. Mohammad Rahbar

##### **Street address**

Golgasht Ave., Imam Reza university hospital, physical medicine and rehabilitation ward

##### **City**

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##### **Postal code**

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##### **Email**

rahbarm@tbzmed.ac.ir

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Neda Dolatkahh

##### **Street address**

Golghasht Ave., Imam Reza hospital, Physical medicine and rehabilitation department.

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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**

Tabriz 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**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Sepideh Ranjbar

##### **Position**

Physical medicine and rehabilitation resident

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Physical Medicine

##### **Street address**

Golghasht Ave., Imam Reza hospital, Physical medicine and rehabilitation department

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant professor of Physical medicine & rehabilitation

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

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**Latest degree**

Medical doctor

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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**

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**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be 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