

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparing the effect of physiotherapy alone and physiotherapy after corticosteroid injection on pain, function, and quality of life in people with shoulder impingement syndrome (A randomized Control Trial)

#### Protocol summary

##### Study aim

Comparing the effect of physiotherapy alone and physiotherapy after corticosteroid injection on pain, function, and quality of life in people with shoulder impingement syndrome

##### Design

Clinical trial, randomized grouping of individuals with sealed envelopes into intervention and control groups, blind assessment of variables by the evaluator

##### Settings and conduct

Place of study: Physical Therapy Clinic of Ghaem Hospital  
Evaluator: The other physiotherapist will evaluate the patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: .aged 18-65 years/pain more than 6 weeks/ pain in the upper, outer arm especially when lifting of arm/ signs of shoulder impingement syndrome (presence of three of the following) 1) painful arch movement during flexion or abduction of the shoulder 2) positive Neer or Hawkins-Kennedy test 3) painful resisted external rotation, or painful jobe test  
Exclusion criteria:  
1.Existence of type 3 acromion 2. Existence of frozen shoulder 3. Existence of neck radiculopathy 4.Existence of Complete rupture of rotator-cuff muscles 5.Existence of shoulder joint instability 6.History of fracture or dislocation or surgery in the shoulder complex 7.Use of Corticosteroids drugs in the last 3 months 8.History of Reflex Sympathetic Dystrophy 9.History of any neurological diseases 10.History of rheumatoid diseases and shoulder osteoarthritis

##### Intervention groups

Physiotherapy alone  
Physiotherapy after corticosteroid injection

##### Main outcome variables

Pain with VAS scale; functional level with Shoulder pain and disability index and Quick DASH questionnaires; quality of life with WORC questionnaire; effectiveness of

treatment with GRC

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201010048980N1**

Registration date: **2020-11-10, 1399/08/20**

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

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

##### Registration date

2020-11-10, 1399/08/20

##### Registrant information

##### Name

Javad Raeesi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3513 7115

##### Email address

reisij961@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2020-12-21, 1399/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effect of physiotherapy alone and physiotherapy after corticosteroid injection on pain, function, and quality of life in people with shoulder impingement syndrome (A randomized Control Trial)

**Public title**

The comparative effect of two methods of rehabilitation in patients with shoulder impingement syndrome

**Purpose**

Treatment

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

Aged 18-65 years/pain more than 6 weeks/ pain in the upper, outer arm especially when lifting of arm/ signs of shoulder impingement syndrome (presence of three of the following) 1) painful arch movement during flexion or abduction of the shoulder 2) positive Neer or Hawkins-Kennedy test 3) painful resisted external rotation, or painful jobe test

**Exclusion criteria:**

1.Existence of type 3 acromion 2. Existence of frozen shoulder 3. Existence of neck radiculopathy 4.Existence of Complete rupture of rotator-cuff muscles 5.Existence of shoulder joint instability 6.History of fracture or dislocation or surgery in the shoulder complex 7.Use of Corticosteroids drugs in the last 3 months 8.History of Reflex Sympathetic Dystrophy 9.History of any neurological diseases 10.History of rheumatoid diseases and shoulder osteoarthritis

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Convenient sampling Randomization Tool: Sealed envelopes include paired and odd numbers (from one to 40) allocation concealment will be done randomly.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants choose to pick one of the sealed envelopes. Another physiotherapist who does not know how to group and do the study will evaluate the patients.

**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**

Opposite University Street 18, University street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9138813944

**Approval date**

2020-09-12, 1399/06/22

**Ethics committee reference number**

IR.MUMS.REC.1399.432

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

Shoulder Impingement Syndrome

**ICD-10 code**

M75.4

**ICD-10 code description**

Impingement syndrome of shoulder

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

Pain intensity

**Timepoint**

Before the start of the treatment plan / after the completion of the treatment plan

**Method of measurement**

Visual analogue scale

**Secondary outcomes****1****Description**

Disability and functional level

**Timepoint**

Before the start of the treatment plan / after the completion of the treatment plan

## Method of measurement

Quick-DASH questionnaire , SPADI questionnaire

## 2

### Description

The quality of life

### Timepoint

Before the start of the treatment plan / after the completion of the treatment plan

### Method of measurement

Western Ontario Rotator Cuff Index Questionnaire (WORK)

## 3

### Description

The effectiveness of the treatment

### Timepoint

Before the start of the treatment plan / after the completion of the treatment plan

### Method of measurement

Global Rating of Change scale (GRC) questionnaire

## Intervention groups

## 1

### Description

Intervention group: For patients, corticosteroids are injected first and after 2 to 4 days, a physiotherapy treatment program will be performed in twelve sessions, within one month. This rehabilitation program includes: correcting the body posture, strengthening the rotator cuff muscles, strengthening the muscles of the scapula, and retraining the muscles of the scapula and shoulders

### Category

Rehabilitation

## 2

### Description

Control group: One-month physical therapy program for twelve sessions. This rehabilitation program includes: correcting the body posture, strengthening the rotator cuff muscles, strengthening the muscles of the scapula, and retraining the muscles of the scapula and shoulders

### Category

Rehabilitation

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Physical Therapy Clinic of Ghaem Hospital

#### Full name of responsible person

Mr Javad Zarandi

#### Street address

Nursing door entrance, right side, library side, Narjes building, first floor, Physiotherapy Department, Ghaem

Hospital,

#### 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 Mohsen Tafaghodi

#### Street address

Doctora Cross road, Ghoreshi Building

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9919191778

#### Phone

+98 51 3841 1538

#### Fax

+98 51 3843 0249

#### Email

vcresearch@mums.ac.ir

#### Web page address

<http://v-research.mums.ac.ir/>

#### Grant name

#### 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

SeyedJavad Raeesi

**Position**

MSc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3513 7115

**Email**

raeesij@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

SeyedJavad Raeesi

**Position**

MSc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3513 7115

**Email**

raeesij@yahoo.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

SeyedJavad Raeesi

**Position**

MSc Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

Azadi Square, East door of Ferdowsi University of Mashhad, University campus- Faculty of Paramedical Sciences

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948964

**Phone**

+98 51 3513 7115

**Email**

raeesij@yahoo.com

**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**

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 reports will be reported in one research paper. Raw data will be delivered to researchers for meta analysis.

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

Starting 6 months after publication

**To whom data/document is available**

For researchers

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

Only for meta-analysis

**From where data/document is obtainable**

raeesij@yahoo.com

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

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

**Comments**