

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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