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

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Email
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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