

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The short-term Effect of adding Subacromial Corticosteroid Injection to Physiotherapy on Pain, Disability, and Effectiveness of Treatment in Patients with Frozen Shoulder: Randomized Controlled Trial

Protocol summary

Study aim

The purpose of this study is to compare the short-term effect of Physiotherapy and Physiotherapy with Subacromial Corticosteroid Injection on Pain, Disability and effectiveness of Treatment in patients with Frozen shoulder.

Design

This clinical trial is a randomized, superiority, parallel, blinded, multicenter study with 48 participants in two groups (24 in each group).

Settings and conduct

After the initial evaluation via the blinded assessor and randomization at Orthopedics clinic of Prof. Mohammad Hossein Ebrahim Zade, injection group will receive the treatment at Orthopedics clinic of Prof. Mohammad Hossein Ebrahim Zade. Both groups will receive the physiotherapy treatment at Special Physiotherapy clinic of Qaem Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients older than 18 years, Abduction and External rotation limitation (More than 50% of normal range), A minimum history of 4 weeks of Shoulder pain, Absence of coagulative diseases, Sleep disturbances due to pain and incapability of sleeping on the affected side. Exclusion criteria: History of severe trauma to the shoulder, History of neck radiculopathy, History of complete Rotator Cuff tear, Severe infection, History of Glenohumeral joint fracture, Presence of malignancy in Shoulder 4 to 6 months after Radiotherapy in Shoulder, Injection contraindications (Allergic to Drug, etc.)

Intervention groups

Comprehensive physiotherapy with hot pack application, low level laser therapy, glenohumeral joint mobilizations and Proprioceptive neuromuscular facilitation techniques. Intra-articular Corticosteroid injection into the glenohumeral joint via the posterior approach.

Main outcome variables

Pain via the Visual Analogue Scale (VAS) and Shoulder Pain and Disability Index (SPADI); Disability via SPADI; The effectiveness of treatment via the Global Rate of Change (GRC) scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161221031506N10**
Registration date: **2023-11-26, 1402/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-26, 1402/09/05**

Update count: **0**

Registration date

2023-11-26, 1402/09/05

Registrant information

Name

Salman Nazary-Moghadam

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-09-15, 1403/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The short-term Effect of adding Subacromial Corticosteroid Injection to Physiotherapy on Pain, Disability, and Effectiveness of Treatment in Patients with Frozen Shoulder: Randomized Controlled Trial

Public title

Comparison of Drug Injection and Physiotherapy in patients diagnosed with Frozen Shoulder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 18 years Abduction and External rotation limitation (More than 50% of normal range) A minimum history of 4 weeks of Shoulder pain Absence of coagulative diseases Sleep disturbances due to pain and incapability of sleeping on the affected side

Exclusion criteria:

History of severe trauma to the shoulder History of neck radiculopathy History of complete Rotator Cuff tear Severe infection History of Glenohumeral joint fracture Presence of malignancy in Shoulder 4 to 6 months after Radiotherapy in Shoulder Injection contraindications (Allergic to Drug, etc)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Using stratified randomization, two indexes of numbers 1 and 2, which belong to physiotherapy (number 1) and physiotherapy with injection (number 2), respectively, will be generated from "sealedenvelope.com" and put into opaque, sealed envelopes. One group of envelopes belongs to diabetic patients and the other group, to non-diabetic patients. Based on the mean and standard deviation of the SPADI questionnaire score in similar Studies, while considering a 10% drop rate, 24 subjects will be allocated to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will choose from sealed, opaque envelopes.

Another physiotherapist who is not aware of the allocation will evaluate the patients in a separate room. Data analyser will be blinded when performing statistical analysis using codes A and B for intervention groups in the statistical analysis software.

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

Mashhad University of Medical Science's Research and Development Deputy Office, Across 18th University Street, University Street.

City

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Province

Razavi Khorasan

Postal code

9177948964

Approval date

2023-08-19, 1402/05/28

Ethics committee reference number

IR.MUMS.REC.1402.133

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

Adhesive capsulitis of shoulder (Frozen Shoulder)

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

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

pain

Timepoint

Immediately After Allocation, 6 weeks after Randomization

Method of measurement

Shoulder Pain and Disability Index (SPADI) questionnaire, Visual Analogue Scale

Secondary outcomes

1

Description

Disability

Timepoint

Immediately After Allocation, 6 weeks after
Randomization

Method of measurement

Shoulder Pain and Disability Index (SPADI) questionnaire

2

Description

The Effectiveness of Treatment

Timepoint

6 weeks after randomization

Method of measurement

Global Rating of Change Scale

Intervention groups

1

Description

Intervention group: First, the treatment will be performed by injecting 1 cc of triamcinolone (40 mg) and 9 cc of 2% lidocaine as a side injection in the subacromial space. After 24 hours of treatment, they will receive 10 sessions of physiotherapy 3 sessions a week. In this group, after applying the hot pack for 15 minutes, a low-power laser will be applied for 30 seconds at 8 painful points of the shoulder joint capsule with 1.8 joules of energy at each point. After that, grade 2 mobilization of the glenohumeral joint will be done in the direction of abduction and external rotation. Then, the second diagonal pattern of flexion in the upper limb in the involved hand along with the Hold-Relax technique will be performed in the form of 10 seconds of contraction of the antagonist muscle, 5 times in each session.

Category

Rehabilitation

2

Description

Control group: In physiotherapy group, who will receive 10 sessions, 3 sessions weekly, after hot pack application for 15 minutes, low level laser with 1.8 joules of energy per point will be applied for 30 seconds on 8 painful points of the glenohumeral capsule. Afterwards, a grade 2 glenohumeral mobilization for improving Abduction and External Rotation will be applied. Finally, the D2 flexion pattern of the involved extremity accompanied by Hold Relax technique, performed with 10 seconds of antagonist muscle contraction, will be applied 5 times per each session.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical Therapy Clinic of Qaem Hospital

Full name of responsible person

Mr. Javad Zarandi

Street address

Narjes building, first floor, Physiotherapy Department,
Qaem Hospital, Nurse Street.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Ghoreshi Building, Doctora Crossroad.

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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

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

Reyhane Rastgou

Position

MSc Colleague

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Faculty of Paramedical Sciences, University campus,
East entrance of Ferdowsi University of Mashhad,
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Position

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Other areas of specialty/work

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Full name of responsible person

Reyhane Rastgou

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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

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 data will be reported in the form of a research article.
Raw data will be delivered to researchers for meta analysis.

When the data will become available and for how long

6 months after publication

To whom data/document is available

For researchers only.

Under which criteria data/document could be used

For meta-analysis Only.

From where data/document is obtainable

rastgour4001@mums.ac.ir

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

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

Comments