Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 Sub-acromial 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

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 6713

Email address

nazaryms@mums.ac.ir

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
Mashhad
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.
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
Ghoreshi Building, Doctora Crossroad.
City
Mashhad
Province
Razavi Khorasan
Postal code
9919191778
Phone
+98 51 3841 1538
Email
vcresearch@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
Reyhane Rastgou

Position
MSc Colleague

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Faculty of Paramedical Sciences, University campus, East entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948964

Phone
+98 51 3869 8719

Email
rastgour4001@mums.ac.ir

Person responsible for scientific 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

Street address
Faculty of Paramedical Sciences, University campus, East entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948964

Phone
+98 51 3869 8719

Email
rastgour4001@mums.ac.ir

Person responsible for updating data

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

Street address
Faculty of Paramedical Sciences, University campus, East entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948964

Phone
+98 51 3869 8719

Email
rastgour4001@mums.ac.ir

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