Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jul 2026

A Comparative study between intra-articular corticosteroid injection and ultrasound-guided hydrodilatation in patients with shoulder adhesive capsulitis

Protocol summary

Study aim
Comparison of hydrodilatation with ultrasound guided intra-articular corticosteroid injection in reducing pain and shoulder range of motion improvement in patients with adhesive capsulitis

Design
The research is a randomized double blind clinical trial on 48 patients

Settings and conduct
Samples are selected from patients with shoulder adhesive capsulitis referred to Imam Reza Clinic divided into two groups The blocked randomized method is used. After obtaining informed consent, In control group methylprednisolone is injected intra-articular and in intervention group 0.9% normal saline is injected intra-articular under ultrasonography guidance and Finally effects on pain reduction and shoulder range of motion improvement are measured.

Participants/Inclusion and exclusion criteria
Presence of pain and shoulder range of motion limitation more than 30 degree in more than two motion plane Presence of pain and shoulder range of motion limitation more than one month Shoulder pain after cerebrovascular attack in paretic side Patients with severe glenohumeral joint osteoarthritis Patients with complete rotator cuff ligaments tear Immune deficiency Fracture in humerus bone or scapula Pregnant women Patients with cancer History of allergy and reaction due in use drugs Shoulder joint rheumatoid arthritis Severe depression Uncontrolled diabetes

Intervention groups
Group A undergoes intra-articular normal saline 0.9% injection in the affected shoulder Group B undergoes intra-articular methylprednisolone injection using ultrasound guide in the affected shoulder

Main outcome variables
Pain, Shoulder range of motion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210910052428N1**
Registration date: **2021-10-12, 1400/07/20**
Registration timing: **prospective**

Last update: **2021-10-12, 1400/07/20**
Update count: **0**

Registration date
2021-10-12, 1400/07/20

Registrant information

Name
Vahide Nadgaran

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3722 2038

Email address
v.nadgaran@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-20, 1400/08/29

Expected recruitment end date
2022-03-19, 1400/12/28

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Comparative study between intra-articular corticosteroid injection and ultrasound-guided hydrodilatation in patients with shoulder adhesive capsulitis

Public title
"Hydrodilatation in adhesive capsulitis", " Intra-articular corticosteroid in adhesive capsulitis"

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Presence of pain and shoulder range of motion limitation more than 30 degree in more than two motion plane Presence of pain and shoulder range of motion limitation more than one month

Exclusion criteria:
Shoulder pain after cerebrovascular attack in paretic side Patients with severe glenohumeral joint osteoarthritis Patients with complete rotator cuff ligaments tear Immune deficiency Fracture in humerus bone or scapula Pregnant women Patients with cancer History of allergy and reaction due in use drugs Shoulder joint rheumatoid arthritis Severe depression Uncontrolled diabetes

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
To match patients in the intervention and control groups, patients are randomly assigned to one of two treatment groups. The random allocation method in this study will be the permutation blocks randomization method with 4 samples in each block and a random list of data will be obtained by using Random Allocation software. We will have two lists of 24 patients, including the two intervention and control groups, at random. For concealment, method of random sequencing is given to another person who is unaware of the research process, and the questionnaires are completed by a person unaware of the division of groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants in study Participant: in this study, we does not have the ability to blind the participant because the participant is aware of receiving each intervention. Clinical care giver: we teach the caregiver how to complete the questionnaire. This person is not aware of receiving patient’s intervention. Researcher: this study does not have the ability to blind the researcher due to performing both interventions by himself and being aware of receiving the kind of intervention in each group. The outcome assessor of the complete questionnaires is given to a person who is not aware of the intervention performed and he/she is asked to determine the level of performance in each person according to the questionnaires. Data analyzer: questionnaire are finally given to a person to review the information. This person does not know any of the steps of the work and the way of classification in which the intervention performed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
No 5/1alley, South eghbale lahoori Ave, Ostad shahriar Ave, Moddaress Blvd

City
Shiraz

Province
Fars

Postal code
7157748857

Approval date
2021-08-30, 1400/06/08

Ethics committee reference number
287.IR .SUMS.MED.REC.1400

Health conditions studied

1

Description of health condition studied
Shoulder adhesive capsulitis

ICD-10 code
M75.00

ICD-10 code description
Adhesive capsulitis of unspecified shoulder

Primary outcomes

1

Description
" Score of pain in visual analoge scale questionnaire" , " Shoulder disability score in shoulder pain and disability index questionnaire"

Timepoint
" Measurement of shoulder range of motion and pain score at the beginning, 2, 4 and 8 weeks after shoulder injection"
Method of measurement
Visual analog scale and shoulder pain and disability index

Secondary outcomes

1

Description
Shoulder Pain
Timepoint
Before intervention; two weeks, four weeks and eight weeks later
Method of measurement
Visual Analogue Scale; Shoulder Pain And Disability Index

2

Description
Shoulder range of motion
Timepoint
Before intervention; two weeks, four weeks and eight weeks later
Method of measurement
With usage of goniometer

Intervention groups

1

Description
Intervention group: injection of normal saline 0.9% with 25cc/sec rate in prevention of capsular rupture due to large amount injection, with injection of 3cc lidocaine under sterile circumstance and with usage of 20 cc syringe in a condition that syringe be parallel to ultrasound probe in semi oblique plane from posterior aspect of shoulder will be done.
Category
Treatment - Drugs

2

Description
Control group: injection of 1 cc methylprednisolone 40 mg/ml plus 1cc lidocaine 2% and 3cc normal saline in a situation that patient is in a prone position and under sterile circumstance and with usage of 20 cc syringe in a condition that syringe be parallel to ultrasound probe in semi oblique plane from posterior aspect of shoulder will be done.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza rehabilitation clinic
Full name of responsible person
Mani Ramzi
Street address
Namazi square
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Postal code
714737-71348
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
خیابان خلیلی، روبروی اموزشگاه معارف
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7134814336
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Info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Vahide Nadgaran

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All available data can be shared after making people unidentifiable.

When the data will become available and for how long
Start access period one year after publishing the results.

To whom data/document is available
Everyone can access to this information.

Under which criteria data/document could be used
If the information in this study helps to improve the science process.

From where data/document is obtainable
Dr.vahide nadgaran v.nadgaran@gmail.com +989171090973

What processes are involved for a request to access data/document
After sending the desired message, all authors of the study will be consulted all information will be sent within a maximum of three weeks if permitted.

Comments