

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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714737-71348

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motahari@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

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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 scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Vahide Nadgaran

Position

Rresident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

Latest degree

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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