

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effect of corticosteroid injection, physiotherapy and combination therapy in frozen shoulder

Protocol summary

Summary

This is a trial on patients with frozen shoulder in order to compare joint injection, physiotherapy and both in a clinic in Sari, Iran. Frozen shoulder is defined as pain and limitation of motion in glenohomeral joint at least 50% in at least two directions. Patients with frozen shoulder for less than one year, the age 18, with total score 30 for SPADI (Shoulder Pain and Disability Index) will entered. Patients with inflammatory arthropathy, degenerative, metabolic (except diabetes), infectious disorders, CVA or fracture or who had received steroid injection or physiotherapy during 6 month ago will exclude. After getting subscription, we will have three groups (1-2-3) that will be divided to 2 blocks (diabetic and non diabetic) with 35 patients in each group randomly, corticosteroid injection in the first group (20 mg triamcinolone in Subacromial bursa and 40 mg triamcinolone in shoulder joint with posterior approach by rheumatologist), physiotherapy in second group (10 sessions shoulder physiotherapy by a physiotherapist for 2 weeks) and both in the third group. Doing simple exercises at home and using Acetaminophen will be recommended in all groups. The patients are evaluated in the weeks of 0, 6 and 24. Intensity of pain and disability are determined according to SPADI questionnaire and physical examination in each visit. Side effects will be recorded in the group of steroid injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138802011828N1**
Registration date: **2009-07-15, 1388/04/24**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2009-07-15, 1388/04/24

Registrant information

Name

Maryam Mobini

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 15 1324 4142

Email address

mmobini@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences and Health services

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-08-23, 1389/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of corticosteroid injection, physiotherapy and combination therapy in frozen shoulder

Public title

Comparison of the effect of corticosteroid injection, physiotherapy and combination therapy in frozen

shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with adhesive capsulitis for less than one year, the age over 18, total score 30 for SPADI
Exclusion criteria: Patients with frozen shoulder accompanied with inflammation, degenerative, metabolic (except diabetes), infectious disorders, CVA or fracture or who had received steroid injection or physiotherapy during 6 months ago.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences and Health Services

Street address

Imam Sq, Joybar 3way, Start of valiye asr highway

City

Sari

Postal code

Approval date

empty

Ethics committee reference number

88-36

Health conditions studied

1

Description of health condition studied

Frozen shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

pain

Timepoint

before intervention and 6 and 24 weeks after intervention

Method of measurement

VAS

2

Description

disability

Timepoint

before intervention and 6 and 24 weeks after intervention

Method of measurement

SPADI questionnaire

Secondary outcomes

1

Description

passive flexion

Timepoint

before intervention and 6,24 weeks after intervention

Method of measurement

Goniometer

2

Description

passive abduction

Timepoint

before intervention and 6,24 weeks after intervention

Method of measurement

Goniometer

3

Description

passive external rotation

Timepoint

before intervention and 6,24 weeks after intervention

Method of measurement

Goniometer

Intervention groups

1

Description

In corticosteroid group: 20 mg triamcinolone +1.5 cc

lidocaine 2% in Subacromial bursa and 40 mg triamcinolone+ 3cc lidocaine 2% in shoulder joint with posterior approach by rheumatologist

Category

Treatment - Drugs

2

Description

In physiotherapy group: 10 sessions shoulder physiotherapy by a physiotherapist for 2 weeks

Category

Treatment - Devices

3

Description

In third group: 20 mg triamcinolone +1.5 cc lidocaine 2% in Subacromial bursa and 40 mg triamcinolone+ 3cc lidocaine 2% in shoulder joint with posterior approach by rheumatologist after one week 10 sessions shoulder physiotherapy by a physiotherapist for 2 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tuba clinic

Full name of responsible person

Marayam Mobini

Street address

Khazar bulvared

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences and Health Services

Full name of responsible person

Sayed jalal Hosseini mehr

Street address

Moalem sq.

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran University of Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of medical sciences and Health services

Full name of responsible person

Motahareh Kheradmand

Position

Master of science nursing

Other areas of specialty/work

Street address

Moallem square

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran university of medical sciences and Health services

Full name of responsible person

Maryam Mobini

Position

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Other areas of specialty/work

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Razi street - Imam Khomani hospital

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Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences and
Health Services

Full name of responsible person

Morteza Yaghubi

Position

Medicine student

Other areas of specialty/work**Street address****City**

Sari

Postal code**Phone****Fax****Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty