Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Maryam Mobini
Name of organization / entity
Mazandaran University of Medical Sciences and Health Services
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Iran (Islamic Republic of)
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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 over18, 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 month 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 questionarie

Secondary outcomes

1

Description
passive flexion

Timepoint
before intervention and 6,24 weeks after intervention

Method of measurement
Goniometer

2

Description
passive abdaction

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 Univercity of medical sciences and Health services

Full name of responsible person

Motahareh Kheradmand

Position

Master of science nursing

Other areas of specialty/work

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Moallem square

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elhamkheradmand2003@yahoo.com; kheradmnd@mazums.ac.ir

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaranl univercity of medical sciences and Health services

Full name of responsible person

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Other areas of specialty/work

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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
Medecine 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