

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of joint mobilization and proprioceptive neuromuscular facilitation (PNF) on pain, range of motion and function of the patients with shoulder adhesive capsulitis; a randomized clinical trial

Protocol summary

Study aim

To determine the additional effect of combined joint mobilization and PNF on pain, function, and range of motion in patients with shoulder adhesive capsulitis

Design

Randomized, superiority, parallel-group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site

Settings and conduct

Sports medicine clinic of Imam khomeini hospital

Participants/Inclusion and exclusion criteria

Inclusion: Age between 40 & 70; Diagnosed unilateral shoulder adhesive capsulitis, as pain, stiffness and limitation of passive movement compared with the opposite side; More than 3 months after the start of symptoms. Exclusion: Other pathologic conditions in shoulder or neck; Severe trauma or fracture; Infection; Pregnancy; Cardiologic, psychiatric, and any other severe diseases impairing the active participation in the study; Any type of manual therapies or intraarticular injections in the course of disease before inclusion in study.

Intervention groups

Intervention group: Intraarticular corticosteroid injection + general exercises + 5 sessions of joint mobilization and PNF Control group: Intraarticular corticosteroid injection + general exercises

Main outcome variables

Pain Function Range of motion in flexion, external rotation, abduction, and internal rotation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111116008117N5**

Registration date: **2021-12-22, 1400/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-22, 1400/10/01**

Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name

Farzin Halabchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2282

Email address

fhalabchi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of joint mobilization and proprioceptive neuromuscular facilitation (PNF) on pain, range of motion and function of the patients with

shoulder adhesive capsulitis; a randomized clinical trial

Public title

Investigating the effect of joint mobilization and PNF on shoulder adhesive capsulitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40 & 70 Diagnosed unilateral shoulder adhesive capsulitis (idiopathic or diabetes-related) as pain, stiffness and more than 50% limitation of passive movement in one or more movements of external rotation, abduction and internal rotation compared with the opposite side More than 3 months after start of symptoms

Exclusion criteria:

Other pathologic conditions in shoulder or neck Severe trauma or fracture Infection Pregnancy Cardiologic, psychiatric, and any other severe diseases impairing the active participation in the study Any type of manual therapies or intraarticular injections in the course of disease before inclusion in study

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization in sizes of 2, 4 and 6 Randomization unit: Individual Randomization tool: Random digits tables The researcher who will assess the outcomes is not aware of the patient allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because the interventions are performed as manual therapies and special exercises, blinding of the participants and care provider is not possible, but the outcome assessors and data analyzers will be blind to the allocation of participants to intervention or control groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of Imam Khomeini Hospital Complex,, Tehran University of Medical Sciences

Street address

Department Sports and Exercise Medicine, Imam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.362

Health conditions studied

1

Description of health condition studied

Adhesive capsulitis of shoulder

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes

1

Description

Pain

Timepoint

before & immediately after intervention period

Method of measurement

VAS score

2

Description

Function

Timepoint

before & immediately after intervention period

Method of measurement

SPADI (Shoulder Pain And Disability Index) score: A 13 items questionnaire to assess function and disability of shoulder with reported good validity and reliability.

Secondary outcomes

1

Description

Range of motion - abduction

Timepoint

Before and immediately after intervention

Method of measurement

Goniometric measurement

Intervention groups

1

Description

Intervention group: Joint mobilization (5X20minutes joint mobilization sessions including PNF D1 & D2 patterns)+ usual care (Intraarticular corticosteroid injection plus home exercises)

Category

Rehabilitation

2

Description

Control group: Usual care (Intraarticular corticosteroid injection plus home exercises)

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sports medicine clinic, Imam Khomeini hospital, Tehran university of medical sciences

Full name of responsible person

Farzin Halabchi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotoohi, Vice Chancellor of research Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital, Keshavarz Blvd.

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Grant name

Vice Chancellor of research - Tehran University of Medical Sciences

Grant code / Reference number

1400-2-101-54488

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Farzin Halabchi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Sport Medicine

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Web page address

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 collected deidentified data

When the data will become available and for how long

12 months after publication

To whom data/document is available

Only for people working in academic institutions

Under which criteria data/document could be used

No specific criteria

From where data/document is obtainable

email of the corresponding person fhalabchi@tums.ac.ir

clinic contact phone: +982161192282

What processes are involved for a request to access data/document

All de-identified data will be provided 1 month after request.

Comments