Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Iran (Islamic Republic of)
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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

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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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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