

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparing the effect of home based exercise and routine physiotherapy on pain and function in patients with adhesive capsulitis of shoulder:a randomized clinical trial

Protocol summary

Summary

The aim of this study is to compare home based exercise to physiotherapy treatment on pain and function of patients with adhesive capsulitis. In this single blind (assessor blinding), phase 3, clinical randomized trial 50 patients (from Firouzgar university hospital, Tehran) suffering from frozen shoulder for more than 3 month, aged between 30 and 65 year and without any systemic disease will be randomly divided into two groups using sealed envelopes. The first group will receive routine physiotherapy treatment including 10 sessions of physical modality and specific stretching and strengthening exercises, while the second group will only be thought the same specific exercises and will be advised to perform them at home and stay as much active as they can. Pain (using visual analogue scale) and function (using oxford shoulder score) will be measured before and after treatment as well as in 2 months follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053021139N6**

Registration date: **2016-06-29, 1395/04/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-29, 1395/04/09

Registrant information

Name

Safoora Ebadi

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 175 7107

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-06-30, 1395/04/10

Expected recruitment end date

2016-09-26, 1395/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of home based exercise and routine physiotherapy on pain and function in patients with adhesive capsulitis of shoulder:a randomized clinical trial

Public title

Comparing exercising at home to routine physiotherapy on frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Having adhesive capsulitis for more than 3 months; No history of surgery or fracture in upper extremity or spine; Not having any systemic disease;

Have not received physiotherapy treatment of any kind during last 6 months; Not pregnant; Not having psychological problems or not using any medicine related to psychological problems
Exclusion Criteria:
Patients who are unwilling to continue treatment;
Violation of any one of inclusion criteria

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization is by using sealed envelopes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City

Tehran

Postal code

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

IR.IUMS.REC 1394.00637663021

Health conditions studied

1

Description of health condition studied

Frozen shoilder

ICD-10 code

M75.0

ICD-10 code description

Frozen shoulder Periarthritis of shoulder

Primary outcomes

1

Description

Pain

Timepoint

Before treatment, After 10 sessions of treatment, In 2 months followup

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Function

Timepoint

Before treatment, After 10 sessions of treatment, In 2months followup

Method of measurement

Oxford Shoulder Score

Intervention groups

1

Description

Intervention group: 10 sessions of physiotherapy 3 days per week including physical modality, mobilization and specific strengthening and stretching exercises at home

Category

Rehabilitation

2

Description

Control group: Learning to perform specific strengthening and stretching exercises at home and being advised to stay active at home

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Dr. Safoora Ebadi

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Javad Ali Musavi

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Iran University of Medical Sciences

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**

Iran University of Medical Sciences; Faculty of Medicine

Full name of responsible person

Dr. Safoora Ebadi

Position

Assistant Professor

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Position

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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