

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Randomized controlled trial to study of efficacy of continuous passive motion device on pain and range of motion in order to improve function, in the patients with shoulder joint stiffness

Protocol summary

Study aim

This is a clinical trial study to improve therapeutic methods and shortening the length of treatment in individuals with shoulder joint stiffness and Determining the Effectiveness of Using CPM Machine on Pain, Range of Motion and Function of Individuals with Frozen Shoulder

Design

In this study, 16 frozen shoulder patients are selected, who have been admitted to the study and come to the referral center. Participants are randomly divided into two groups of intervention and control

Settings and conduct

The statistical population in this study includes all individuals with shoulder joint stiffness in Tehran aged between 40 to 65 years old. Convenience sampling method will be used, then patients randomly will be divided into two groups of standard treatments including usage of CPM device (intervention group) and standard intervention (control group) with a sample size of 8 per group.

Participants/Inclusion and exclusion criteria

The inclusion criteria included individuals with shoulder joint stiffness diagnosed in second stages of disease and at least 3 months passes of the onset of their disease

Intervention groups

Intervention group: A group that uses CPM devices in addition to receiving common exercises treatment.
Control group: A group that only receives common exercises treatment

Main outcome variables

Reduce pain, Increase the range of motion, Improve performance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170719035173N2**

Registration date: **2018-01-23, 1396/11/03**

Registration timing: **retrospective**

Last update: **2018-01-23, 1396/11/03**

Update count: **0**

Registration date

2018-01-23, 1396/11/03

Registrant information

Name

hamideh azizi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences

Country

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Recruitment status

Recruitment complete

Funding source

institution

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-01-08, 1396/10/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized controlled trial to study of efficacy of continuous passive motion device on pain and range of motion in order to improve function, in the patients with shoulder joint stiffness

Public title

Efficacy of continuous passive motion device in the shoulder joint stiffness

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of shoulder joint stiffness Symptoms of stage 2 of disease Expired at least 3 months from the onset of the disease Age between 40-65

Exclusion criteria:

Herniation of cervical disks Joint shoulder stiffness due to neurological disease Injury during the study

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are placed in one of the two intervention or control groups using sealed envelopes and receive intervention from the same group.

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

University of Social Welfare and Rehabilitation Sciences

Street address

Daneshjoo Blvd, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985713834

Approval date

2017-06-22, 1396/04/01

Ethics committee reference number

IR.USWR.REC.1396.17

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

At the initial of the threatment, 4, 6 Weeks

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Shoulder range of motion

Timepoint

The initial of the threatment, 4, 6 weeks

Method of measurement

Goniometry

Intervention groups

1

Description

Intervention: conservative treatment and CPM device

Category

Rehabilitation

2

Description

Control group: conservative treatment

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Asma rehabilitation center

Full name of responsible person

Maryam Farzad

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Corner of Twelve St, Asad Abadi Street, Yousef Abad

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Full name of responsible person

Hamideh Azizi

Position

Student of Master of Science of Occupational Therapy

Latest degree

Bachelor

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Department of Occupational Therapy

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

Yes

Title of funding source

University of Social Welfare and Rehabilitation 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**

University of Social Welfare and Rehabilitation Sciences

Person responsible for scientific inquiries**Contact****Name of organization / entity**

University of Social Welfare and Rehabilitation Sciences

Full name of responsible person

Maryam Farzad

Position

PHD of Occupational Therapy

Latest degree

Ph.D.

Other areas of specialty/work

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Hamideh Azizi

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Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available