

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

comparative effect of physiotherapy and corticosteroid injection on pain, disability and quality of life in patients with impingement syndrome

Protocol summary

Study aim

Comparative effect of evidence-based physiotherapy and corticosteroid injection on pain, disability, effectiveness of treatment and quality of life in patients with subacromial impingement syndrome

Design

two arm parallel group randomized controlled trial with blinded therapist. patients randomized with number of groups in envelop package . 25 patients between 16 to 65 years enrolled in this RCT

Settings and conduct

this trial will done in physiotherapy and orthopedic department of Ghaem and Emam Reza hospital, Mashhad, Iran

Participants/Inclusion and exclusion criteria

patients with impingement sign between 16 to 6 years. Participants were excluded if they presented one of the following: 1) previous shoulder surgery, dislocation or fracture; 2) shoulder pain reproduced by active or passive neck movement; 3) clinical signs of full-thickness rotator cuff tear; 4) frozen shoulder; 5) patients with less duration than 2 months; and 6) patients who didn't live in Mashhad

Intervention groups

patients in physiotherapy and injection group

Main outcome variables

Pain, disability, quality of life and effectiveness of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180109038285N1**

Registration date: **2018-12-04, 1397/09/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-04, 1397/09/13**

Update count: **0**

Registration date

2018-12-04, 1397/09/13

Registrant information

Name

Maryam Daghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3752 9812

Email address

maryamdaghighi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-09, 1396/10/19

Expected recruitment end date

2020-01-09, 1398/10/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparative effect of physiotherapy and corticosteroid injection on pain, disability and quality of life in patients with impingement syndrome

Public title

comparative effect of physiotherapy and corticosteroid injection on pain, disability and quality of life in patients with impingement syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with impingement syndrome signs for more than 4 weeks pain level between 3 and 7 in VAS scale

Exclusion criteria:

full thickness rotator cuff tear neck pain adhesive capsulitis/ frozen shoulder history of shoulder girdle subluxation or fracture in past 3 months

Age

From **16 years** old to **68 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomized method will be used that is equal to the number of people in each group and the tool is hidden envelope. Groupings are hidden in the envelope in the package that the physician uncovers the envelope randomly and identifies it and defines the grouping.

Blinding (investigator's opinion)

Double blinded

Blinding description

the therapist is not alert about groping and assessing and assessor is not involving in treatment.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of mashhad university of medical science

Street address

mashhad, shahid kalantari Blv, mashhad university of medical science

City

mashhad

Province

Razavi Khorasan

Postal code

1234567891

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.MUMS.REC.1397.090

Health conditions studied

1

Description of health condition studied

impingement syndrome

ICD-10 code

M75.5

ICD-10 code description

Bursitis of shoulder

Primary outcomes

1

Description

shoulder pain and disability index, disability of arm shoulder hand

Timepoint

Pre and 4 weeks after randomization

Method of measurement

shoulder pain and disability index questionnaire, disability of arm, shoulder, hand questionnaire

Secondary outcomes

1

Description

pain intensity

Timepoint

pre and 4 weeks after randomization

Method of measurement

10 cm ruler as measuring scale

2

Description

quality of life

Timepoint

pre and 4 weeks after randomization

Method of measurement

western ontario rotator cuff index questionnaire

3

Description

global rating of change

Timepoint

pre and 4 weeks after randomization

Method of measurement

question about effectiveness of treatment

4

Description

disability of shoulder intensity

Timepoint

pre and 4 weeks after randomization

Method of measurement

SPADI and Quick-DASH questionnaire

Intervention groups**1****Description**

Intervention group: Physiotherapy treatment group based on patient assessment and focus on the treatment of disorders. This treatment includes: correcting the body posture, strengthening the rotator cuff muscles, strengthening the muscles of the scapula and retraining the muscles of the scapula and shoulders.

Category

Rehabilitation

2**Description**

Intervention group: The corticosteroid injection group, which the orthopedic surgeon injects 1 cc triamhexal and 2 cc lidocaine, using the anterolateral approach to the person's affected shoulder.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem hospital

Full name of responsible person

Dr. Hossein Negahban

Street address

Ghaem hospital, Ahmad abad Ave, Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9596126532

Phone

+98 51 3752 9810

Email

maryamdaghiani@yahoo.com

2**Recruitment center****Name of recruitment center**

Emam Reza hospital

Full name of responsible person

Dr. Ahmad Ajvadi

Street address

Emam Reza squ

City

mashhad

Province

Razavi Khorasan

Postal code

9691236532

Phone

+98 51 3842 9092

Email

maryamdaghiyani@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen tafaghodi

Street address

mashhad university of medical science, Azadi squ

City

mashhad

Province

Razavi Khorasan

Postal code

9694565321

Phone

+98 51 3884 6715

Email

tafaghodim@mums.ac.ir

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Hossein Negahban sioki

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Mashhad university of medical science, Azadi Squ,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9896532150

Phone

+98 51 3884 6726

Email

honegahban@yahoo.com

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

Mashhad University of Medical Sciences

Full name of responsible person

Doctor Hossein Negahban sioki

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Mashhad university of medical science, Azadi Squ,
Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9896532150

Phone

+98 51 3884 6726

Email

honegahban@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Daghiyani

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

No 42, la'l Ave 4, Pardis Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

9695123620

Phone

+98 51 3752 9810

Fax**Email**

maryamdaghiyani@gmail.com

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

after hiding of personal information, demographic data
will be useable

When the data will become available and for how long

data will be usable 6 months after publishing

To whom data/document is available

It will be available to scholars working in academia and
academia, and people who are engaged in the industry.

Under which criteria data/document could be used

If needs information to use research in universities, it will
be used after confirming the ethics code

From where data/document is obtainable

To receive the data / documentation, contact Dr. Hossein
Sioki and send it via e-mail after the reason is provided.
Email Dr. Hossein Sioki is: honegahban@yahoo.com or
by contacting Ms. Maryam Daghiyani, and after providing
the reason, the data will be provided to them. her e-mail
is: maryamdaghiyani@gmail.com

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

It is imperative that the explanation of the need for data
is sufficiently given and the characteristics of the
research plan to be addressed.

Comments