Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
tow 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 Daghiani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3752 9812
Email address
maryamdaghiyani@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 sublaxation 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 ortopedic 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 sience, 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 sience, 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 sience, 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 Daghiani
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 Daghiani, 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