Comparing the effect of physiotherapy alone and physiotherapy after corticosteroid injection on pain, function, and quality of life in people with shoulder impingement syndrome (A randomized Control Trial)

Protocol summary

Study aim
Comparing the effect of physiotherapy alone and physiotherapy after corticosteroid injection on pain, function, and quality of life in people with shoulder impingement syndrome

Design
Clinical trial, randomized grouping of individuals with sealed envelopes into intervention and control groups, blind assessment of variables by the evaluator

Settings and conduct
Place of study: Physical Therapy Clinic of Ghaem Hospital
Evaluator: The other physiotherapist will evaluate the patients.

Participants/Inclusion and exclusion criteria
Inclusion criteria: aged 18-65 years/pain more than 6 weeks/pain in the upper, outer arm especially when lifting of arm/ signs of shoulder impingement syndrome (presence of three of the following) 1) painful arch movement during flexion or abduction of the shoulder 2) positive Neer or Hawkins-Kennedy test 3) painful resisted external rotation, or painful jobe test

Intervention groups
Physiotherapy alone Physiotherapy after corticosteroid injection

Main outcome variables
Pain with VAS scale; functional level with Shoulder pain and disability index and Quick DASH questionnaires; quality of life with WORC questionnaire; effectiveness of treatment with GRC
Comparing the effect of physiotherapy alone and physiotherapy after corticosteroid injection on pain, function, and quality of life in people with shoulder impingement syndrome (A randomized Control Trial)

The comparative effect of two methods of rehabilitation in patients with shoulder impingement syndrome

Inclusion/Exclusion criteria:
Inclusion criteria:
Aged 18-65 years/pain more than 6 weeks/ pain in the upper, outer arm especially when lifting of arm/ signs of shoulder impingement syndrome (presence of three of the following) 1) painful arch movement during flexion or abduction of the shoulder 2) positive Neer or Hawkins-Kennedy test 3) painful resisted external rotation, or painful jobe test

Exclusion criteria:

Age
From 18 years old to 65 years old

Gender
Both

Groups that have been masked
• Participant
• Investigator
• Outcome assessor
• Data analyser
• Data and Safety Monitoring Board

Sample size
Target sample size: 40

Randomization (investigator’s opinion)
Randomized

Randomization description
Convenient sampling Randomization Tool: Sealed envelopes include paired and odd numbers (from one to 40) allocation concealment will be done randomly.

Blinding (investigator’s opinion)
Double blinded

Blinding description
Participants choose to pick one of the sealed envelopes. Another physiotherapist who does not know how to group and do the study will evaluate the patients.

Placebo
Not used

Primary outcomes

Description of health condition studied
Shoulder Impingement Syndrome

ICD-10 code
M75.4

ICD-10 code description
Impingement syndrome of shoulder

Secondary outcomes

Description
Disability and functional level

Timepoint
Before the start of the treatment plan / after the completion of the treatment plan

Assignment
Parallel
Method of measurement
Quick-DASH questionnaire, SPADI questionnaire

Description
The quality of life

Timepoint
Before the start of the treatment plan / after the completion of the treatment plan

Method of measurement
Western Ontario Rotator Cuff Index Questionnaire (WORK)

Description
The effectiveness of the treatment

Timepoint
Before the start of the treatment plan / after the completion of the treatment plan

Method of measurement
Global Rating of Change scale (GRC) questionnaire

Intervention groups

1 Description
Intervention group: For patients, corticosteroids are injected first and after 2 to 4 days, a physiotherapy treatment program will be performed in twelve sessions, within one month. This rehabilitation program 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
Control group: One-month physical therapy program for twelve sessions. This rehabilitation program 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

Recruitment centers

1 Recruitment center
Name of recruitment center
Physical Therapy Clinic of Ghaem Hospital
Full name of responsible person
Mr. Javad Zarandi
Street address
Nursing door entrance, right side, library side, Narjes building, first floor, Physiotherapy Department, Ghaem Hospital,
City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3841 1538
Email
ZarandiMJ1@mums.ac.ir

Sponsors / Funding sources

1 Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Doctora Cross road, Ghoreshi Building
City
Mashhad
Province
Razavi Khorasan
Postal code
9919191778
Phone
+98 51 3841 1538
Fax
+98 51 3843 0249
Email
vcresearch@mums.ac.ir
Web page address
http://v-research.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
Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
SeyedJavad Raeesi
Position
MSc Student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Azadi Square, East door of Ferdowsi University of Mashhad, University campus, Faculty of Paramedical Sciences
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948964
Phone
+98 51 3513 7115
Email
raeesij@yahoo.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
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

Title and more details about the data/document
All reports will be reported in one research paper. Raw data will be delivered to researchers for meta analysis.

When the data will become available and for how long
Starting 6 months after publication

To whom data/document is available
For researchers

Under which criteria data/document could be used
Only for meta-analysis

From where data/document is obtainable
raeesij@yahoo.com

What processes are involved for a request to access data/document
The response will be sent within 3 months after considering the researcher’s request.

Comments