Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Comparative Effect of Comprehensive Physical therapy with Focus on Scapula and Glenohumeral Joint versus Common Physical Therapy on Pain, Range of motion, Disability Level, Quality of Life and the Effectiveness of Treatment Parameters in Patients with Shoulder Impingement Syndrome

Protocol summary

Study aim

The Comparative Effect of Comprehensive Physical therapy with Focus on Scapula and Glenohumeral Joint versus Common Physical Therapy in treatment of 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 at least two 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, abduction or painful jobe test exclusion criteria: 1.Existence of type 3 acromion 2. Existence of frozen shoulder 3. Existence of neck radiculopathy 4.Existence of Complete rupture of rotator-cuff muscles 5.Existence of shoulder joint instability 6.History of fracture or dislocation or surgery in the shoulder complex 7.Use of Corticosteroids drugs in last 3 months 8.History of Reflex Sympathetic Dystrophy 9.History of any neurological diseases 10.History of rheumatoid diseases and shoulder osteoarthritis

Intervention groups

In the intervention group, a comprehensive physiotherapy focusing on scapula and shoulder joint, and in the control group a common physiotherapy in the shoulder joint will be performed.

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

General information

Reason for update

This update is done to inform the completion of treatment, increase the sample size as well as increase the evaluation time to six months after treatment.

Acronym

IRCT registration information

IRCT registration number: **IRCT20161221031506N2**
Registration date: **2018-06-29, 1397/04/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**
Update count: **1**

Registration date

2018-06-29, 1397/04/08

Registrant information

Name

Salman Nazary-Moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3884 6713

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nazaryms@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-06-05, 1397/03/15

Expected recruitment end date
2019-09-06, 1398/06/15

Actual recruitment start date
2018-06-05, 1397/03/15

Actual recruitment end date
2019-08-05, 1398/05/14

Trial completion date
2019-09-21, 1398/06/30

Scientific title
The Comparative Effect of Comprehensive Physical therapy with Focus on Scapula and Glenohumeral Joint versus Common Physical Therapy on Pain, Range of motion, Disability Level, Quality of Life and the Effectiveness of Treatment Parameters in Patients with Shoulder Impingement Syndrome

Public title
The comparative effect of two physiotherapy methods in patients with shoulder impingement syndrome

Purpose
Treatment

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 at least two 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, abduction or painful jobe (empty can) test

Exclusion criteria:
Existence of type 3 acromion Existence of frozen shoulder (the loss in passive shoulder range of motion greater than 50% as compared to the uninvolved side in at least 2 shoulder movements) Existence of neck radiculopathy Existence of Complete rupture of rotator cuff muscles (MRI findings) Existence of shoulder joint instability (Positive tests of sulcus or apprehension) Use of corticosteroid drugs in last 3 months History of RSD History of any neurological diseases History of rheumatoid diseases and shoulder osteoarthritis History of fracture or dislocation or surgery in the shoulder complex

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Actual sample size reached: **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

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Mashhad University of Medical Sciences

Street address
Opposite University Street 18, University street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2018-05-19, 1397/02/29

Ethics committee reference number
IR.MUMS.REC.1397.056

Health conditions studied

1

Description of health condition studied
impingement syndrome of shoulder

ICD-10 code
M75.4

ICD-10 code description
Impingement syndrome of shoulder

Primary outcomes

1

Description
functional level

Timepoint
Before the start of the treatment plan / after the

completion of the treatment plan / one month after the completion of the treatment plan/ Six month after the completion of the treatment plan

Method of measurement

Shoulder pain and disability index questionnaire

Secondary outcomes

1

Description

pain

Timepoint

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

Method of measurement

visual analogue scale

2

Description

functional level

Timepoint

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

Method of measurement

Quick The Disabilities of the Arm, Shoulder and Hand Score questionnaire

3

Description

quality of life

Timepoint

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

Method of measurement

Western ontario rotator cuff questionnaire

4

Description

The effectiveness of the treatment

Timepoint

Before the start of the treatment plan / after the completion of the treatment plan / one month after the completion of the treatment plan/ six month after the completion of the treatment plan

Method of measurement

global rating of change scale

Intervention groups

1

Description

Intervention group: One-month Physical therapy program with focus on scapula and glenohumeral joint (shoulder) for twelve sessions

Category

Rehabilitation

2

Description

Control group: One-Months Physical Therapy Program at the shoulder joint for twelve sessions

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,

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ZarandiMJ1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Doctora Cross road, Ghoreshi Building

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Web page address
http://v-research.mums.ac.ir/
Grant name
Personal Grant (Dr Salman Nazary-Moghadam)
Grant code / Reference number
961343
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, 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
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Position
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Latest degree
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
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 metaanalysis

From where data/document is obtainable

Nazary_salman@yahoo.com

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

The response will be sent 3 months after considering the researcher request.

Comments