Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the short-term effects of routine physiotherapy and physiotherapy with emphasis on the scapulothoracic joint on pain, range of motion, functional ability and quality of life after arthroscopic shoulder rotator cuff tendon repair.

Protocol summary

Study aim
The aim of this study is to compare the effect of routine physiotherapy and physiotherapy focusing on scapulothoracic joint in patients with rotator cuff arthroscopic repair.

Design
A two-arm pragmatic, parallel-group, single-blind, randomized controlled trial

Settings and conduct
Patients' surgery is performed by an orthopedic specialist and after the operation and evaluation, if they are eligible to enter the study, they are referred to the special physiotherapy clinic of Ghaem Hospital. The assessor and statistician will be blind to the groupings during the project. Random grouping of people will be done by sealed envelopes

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 30-75 years • The origin of the rupture should be progressive damage • The size of the rupture is small and medium (= <3 cm) Exclusion criteria: • Any complication in the shoulder girdle area such as arthritis of the shoulder joint or destructive joint disease as well as SLAP and Bankart surgery • Traumatic tears that result from direct trauma or injury and tears larger than 3 cm • Existence of neurological disorders such as disorders Neurological with sensory and muscular problems • Radicular pain from the neck or chest • History of fracture, dislocation, or shoulder complex surgery

Intervention groups
In the routine physiotherapy group, the treatment program includes pendulum exercises, stretching techniques, manual techniques, and the rotator cuff muscle strengthening program. Therapeutic modalities are also used in each session. In the comprehensive physiotherapy group, in addition to the treatment program mentioned in the routine group, manual techniques include manual therapy of the scapula and thoracic spine, training of the correct position of the scapula at rest, movement control.

Main outcome variables
Pain, Range of Motion, Disability, Functional level, Quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201010048978N1**
Registration date: **2021-04-20, 1400/01/31**
Registration timing: **retrospective**

Last update: **2021-04-20, 1400/01/31**
Update count: **0**

Registration date
2021-04-20, 1400/01/31

Registrant information

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Marzieh Rezaie

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-13, 1399/06/23
Expected recruitment end date
2021-03-13, 1399/12/23
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the short-term effects of routine physiotherapy and physiotherapy with emphasis on the scapulothoracic joint on pain, range of motion, functional ability and quality of life after arthroscopic shoulder rotator cuff tendon repair.

Public title
The comparative effect of two methods of rehabilitation in patients after arthroscopic shoulder rotator cuff tendon repair.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 30-75 years The origin of the rupture should be progressive damage The size of the rupture is small and medium (= <3 cm) Patients with complete rupture of the rotator-cuff muscles except subscapularis Since this operation is usually performed in conjunction with other restorative procedures such as subacromial decompression and distal clavicle resection; to increase the generalizability to the community in this study, patients can be accompanied by these operations.
Exclusion criteria:
Any complication in the shoulder girdle area such as arthritis of the shoulder joint or destructive joint disease as well as SLAP and Bankart surgery Traumatic tears that result from direct trauma or injury and tears larger than 3 cm Existence of neurological disorders such as disorders Neurological with sensory and muscular problems Radicular pain from the neck or chest (Increased/developed shoulder symptoms with active or inactive neck movement) History of fracture, dislocation or shoulder complex surgery History of RSD History of recurrent dislocation or joint instability Shoulder in the last 3 months Symptoms of preoperative capsular adhesion characterized by a loss of more than 50% of inactive range of motion compared to the non-involved side in at least two shoulder movements
Age
From **30 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, randomization is performed by an independent therapist using the block randomization method. In order to assign 15 patients in each group equally, we will use numbers between 1 and 30 for randomization, with even numbers representing the intervention group and odd numbers representing the control group. The reason for performing block randomization is to have the same number of samples in each group. The numbers are written on paper and placed in opaque sealed envelopes, and stamped. Those who meet the inclusion criteria are asked to pick up an envelope, and depending on whether the number in the envelope is even or odd, the patient will be randomly assigned.
Blinding (investigator's opinion)
Single blinded
Blinding description
The trial assessor and statistician were blinded to the treatment allocation throughout the study period.
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
2020-09-12, 1399/06/22
Ethics committee reference number
IR.MUMS.REC.1399.415

Health conditions studied

1

Description of health condition studied
Complete rotator cuff tear or rupture not specified as traumatic

ICD-10 code
S46.0
ICD-10 code description
Injury of muscle(s) and tendon(s) of the rotator cuff of shoulder

Primary outcomes

1

Description
Pain intensity
Timepoint
Before the start of the treatment plan/after the completion of the treatment plan
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Range of motion
Timepoint
Before the start of the treatment plan (two weeks after the surgery) and after the completion of the treatment plan (9 weeks after the surgery)
Method of measurement
Goniometer

2

Description
Disability
Timepoint
Before the start of the treatment plan (two weeks after the surgery) and after the completion of the treatment plan (9 weeks after the surgery)
Method of measurement
SPADI questionnaire

3

Description
The quality of life
Timepoint
Before the start of the treatment plan (two weeks after the surgery) and after the completion of the treatment plan (9 weeks after the surgery)
Method of measurement
Western Ontario Rotator cuff index questionnaire(Worc)

4

Description
The effectiveness of treatment
Timepoint
Before the start of the treatment plan (two weeks after the surgery) and after the completion of the treatment plan (9 weeks after the surgery)
Method of measurement
Global Rating of Scale(GRC) questionnaire

5

Description
Functional level
Timepoint
Before the start of the treatment plan (two weeks after the surgery) and after the completion of the treatment plan (9 weeks after the surgery)
Method of measurement
ASES questionnaire

Intervention groups

1

Description
Intervention group: Postoperative information and intervention if eligible to enter the study after 2 weeks of a rehabilitation program. Physiotherapy treatment in both groups was 21 sessions in 7 consecutive weeks and three sessions per week. Besides the conventional physiotherapy program, this program includes manual techniques to help the scapula and thoracic spine, training the correct position of the scapula at rest, movement control and strengthening of the lower, middle, and serratus trapezius, along with exercises to facilitate multifunctional deep sensation.
Category
Rehabilitation

2

Description
Control group: After surgery and evaluation, patients will start a rehabilitation program after 2 weeks if they are eligible to enter the study. Physiotherapy treatment is 21 sessions that will be done in 7 consecutive weeks and three sessions per week. This rehabilitation program includes: pendulum exercises, stretching techniques, manual techniques including manual treatment of glenohumeral joint (lower and posterior glide of the humerus) and rotator cuff muscle strengthening program. Therapeutic modalities are also used in each session.
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Mohsen Tafaghodi
Street address
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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
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Position
MSc student
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Latest degree
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Other areas of specialty/work

Physiotherapy

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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 6months 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

marzie.rezaee73@gmail.com

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

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

Comments