Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The comparison of clinical outcome of early motion versus late motion following arthroscopic repair of rotator cuff tearing; Randomized Clinical Trial Study

Protocol summary

Study aim

General and specific goals - The main objectives of the project: to compare the effect of physiotherapy immediately and 4 weeks after arthroscopic repair of small and medium rotator cuff tears on the result Therapy: A clinical trial study

Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, was performed on 22 patients and Excel software rand function was used for randomization.

Settings and conduct

Procedure 22 patients undergoing arthroscopic treatment of small to medium rotator cuff tears in Tehran at Imam Khomeini Hospital Are included in the study. All repairs are performed with the same technique Maybe. After the operation, patients will be randomly divided into one of two groups using a table of random numbers. first group They are introduced to physiotherapy immediately after the operation, but the second group will start physiotherapy after 4 weeks. One-sided study Will be blind and the physician evaluating the effect of the treatment is in groups {immediately after surgery and 4 weeks after} unaware.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with full-thickness rotator cuff rupture detected by MRI, including patients with acute rupture or chronic rupture Fractures that involve only the supraspinatus and are in grade 1 or grade 2 coronary MRI Exclusion criteria: 1 - Age under 18 years 2 - Other diseases of the shoulder joint such as infection, avascular necrosis, and so on

Intervention groups

We divided the patients into two groups. The group for whom physical therapy is started immediately after rotator cuff arthroscopic repair. The second group is immobilized for 4 weeks and after 4 weeks physiotherapy is started.

Main outcome variables

Postoperative pain rate. Postoperative functional outcome.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210526051412N1**
Registration date: **2021-06-05, 1400/03/15**
Registration timing: **prospective**

Last update: **2021-06-05, 1400/03/15**
Update count: **0**

Registration date

2021-06-05, 1400/03/15

Registrant information

Name

Sadula Sharifpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3424 0587

Email address

sadulasharifpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of clinical outcome of early motion versus late motion following arthroscopic repair of rotator cuff tearing; Randomized Clinical Trial Study

Public title

The comparison of clinical outcome of early motion versus late motion following arthroscopic repair of rotator cuff tearing; Randomized Clinical Trial Study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with full-thickness rotator cuff rupture diagnosed by MRI include patients with acute rupture or chronic rupture Ruptures involving only the supraspinatus on a grade 1 or grade 2 coronary MR

Exclusion criteria:

1 - Age under 18 years 2 - Other diseases of the shoulder joint such as infection, avascular necrosis and so on Major medical disease that makes it unlikely to live under 2 years 4. A specific psychiatric illness that impairs the possibility of conscious satisfaction .5 - Inability to speak or read Persian 6 - Large ruptures or massive rotator cuff with extension to the subscapularis and minor fear 7 - Simultaneous pathology in labrum that requires surgery 8 - Simultaneous pathology in the acromioclavicular joint that requires distal clavicle resection. 9- Age over 70 years

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each sample is either in the physiotherapy category immediately after surgery or in the physiotherapy category with a delay of 4 weeks

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we use the restricted randomization method randomization (block randomization type randomization (we will use. blocking usually in order Balance the number of samples assigned to each group To be used in the study. This feature helps researchers to Items that require intermediate analyzes during the sampling process The number of samples assigned to each of the case groups The study is equal. The size of all the blocks is equal and we are in this Two-group trial of 6 blocks (including 3 participants in We will have an intervention group and 3 participants in the control group. Randomization tools are also used in sequence generation software Random (software allocation Random) is used that Random sequence generation software in addition to simple randomization capable To produce random sequences by block generation method. For hiding We avoid concealment allocation We use the method used to execute the sequence Random refers to study participants, in a way That before the individual is assigned, the assigned group is not specified. With From opaque envelopes sealed in random sequence (envelopes opaque, sealed, numbered Sequentially) This method uses each of the random sequences created on a card It is registered and the cards are placed in the letter envelopes in order To be. In order to maintain a random sequence, also on the outer surface of the envelope The numbering is done in the same way. Finally the envelope door The letters are pasted and placed in a box, respectively. At Time to start registration of participants, based on the order of entry of the company Eligible applicants to open one of the envelopes in order And the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study will be blinded one way. Patients according to type Interventions will not be blinded. The researcher must enter the data into the checklist The corresponding slow will be blinded to the type of intervention. The person in charge of the clinical care of the patients, as well as the physiotherapist, will not be blinded

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran, Keshavarz Blvd., Imam Khomeini Hospital

City

tehran

Province

Tehran

Postal code

1399/06/12

Approval date

2020-09-01, 1399/06/11

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.205

Health conditions studied

1

Description of health condition studied
Arthropocytic treatment of rotator cuff tear
ICD-10 code
M75.1
ICD-10 code description
Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description
In this study, we want to compare the amount of shoulder forward flexion based on the physiotherapy group immediately and the physiotherapy group 4 weeks later.
Timepoint
It is at intervals of 3, 6 weeks, 3, and 6 months after rotator cuff arthroscopic repair. weeks, 3 months, and six months. will be measured
Method of measurement
With a questionnaire and through the scoring system is the Constant Murley scoring system, which scores between zero and one hundred.

Secondary outcomes

1

Description
Ultrasound 6 after arthroscopic repair of rotator cuff tearing
Timepoint
6 months after surgery
Method of measurement
By sonography and according to the criteria of Sugaya and radiologist

Intervention groups

1

Description
Intervention group: Physiotherapy is performed immediately after arthroscopic repair surgery, ie from the day after the operation. The duration of each session is 30 minutes and 3 sessions per week and the total number of sessions is 30 sessions. TENS, IR, EXE, US modals will be used equally in all patients. All patients with inactive shoulder movements will start from the first session. . All patients will receive physiotherapy at a center by a physiotherapist.
Category
Rehabilitation

2

Description
Control group: Shoulder physiotherapy 4 weeks after arthroscopic repair surgery begins as 3 sessions of shoulder physiotherapy per week with 30 sessions with the emphasis on passive movements and performing tens and exercise and ultrasound and IR.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital Hospital Complex
Full name of responsible person
Sadula Sharifpour
Street address
The end of Keshavarz Boulevard
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 8899 5871
Email
sadulasharifpour@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Moharami
Street address
No. 10 - 4th Floor,Haghshenas Alley,Sabet St.,Forsat Shirazi St.,Enghelab Square
City
tehran
Province
Tehran
Postal code
1418813675
Phone
+98 21 6643 5786
Email
sadulasharifpour@gmail.com
Grant name
10000000
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source

Vice Chancellor for Research and Technology, Tehran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Tehran University of Medical Sciences

Full name of responsible person
Sadula Sharifpour

Position
Orthopedic Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

Street address
Office of the Director of the Orthopedic Department. Imam Khomeini Hospital Complex. End of Keshavarz Boulevard.

City
Tehran

Province
Tehran

Postal code
1418813675

Phone
+98 21 6643 5786

Fax

Email
sadulasharifpour@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Nima Bagheri

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Sabet Street

City
Tehran

Province
Tehran

Postal code
1418813675

Phone
+98 21 6643 5786

Email
nimab1360@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Sadula Sharifpour

Position
Orthopedic Resident

Latest degree
Medical doctor

Other areas of specialty/work
Orthopedics

Street address
Office of the Director of the Orthopedic Department. Imam Khomeini Hospital Complex. End of Keshavarz Boulevard.

City
Tehran

Province
Tehran

Postal code
1418813675

Phone
+98 21 6643 5786

Fax

Email
sadulasharifpour@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
In this section, patient information such as age, sex, and body mass index are published publicly, but patient names are not published.

When the data will become available and for how long
After confirming the ERCT code, we will start the study and 8 months later the data will be available to the public

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

We will make the data available to reputable scientific journals or orthopedic field research researchers in an unidentifiable individual manner.

From where data/document is obtainable

1- Email correctly to sadulasharifpour@gmail.com 2- Call the mobile number 09214736009

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

The applicant will be provided with the identity of the applicant within one week after the initial request

Comments