

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Examining the separate and combined effects of physiotherapy treatment and corticosteroid injection on range of motion and pain in patients with full thickness rotator cuff tear referring to the specialized clinic in Dezful city.

Protocol summary

Study aim

Determining the separate and combined effects of physiotherapy and corticosteroid injection on range of motion and pain in patients full thickness rotator cuff tear

Design

A clinical trial with control group, with parallel groups, randomized

Settings and conduct

96 patients are sampled in a randomized block method. After giving some explanations about the plan and research steps to the patients and obtaining consent, they are divided into 3 groups of 33 people. First, DASH questionnaire and VAS criterion will be completed by these three groups and the motor function of them will be measured by goniometer. The first group will receive physiotherapy, the second group will receive corticosteroid injection and the third group will receive physiotherapy and corticosteroid injection. At the end of intervention, pain and motor function of the patients will be examined by DASH questionnaire and VAS criterion and are measured by goniometer by rehabilitation specialist and orthopaedic physician established in Dezful city and by medical student. At the end of the study, the data results before and after the intervention of these 3 groups will be compared.

Participants/Inclusion and exclusion criteria

Patients with degenerative rotator cuff tear confirmed by MRI and clinical examination, are excluded from the study if they are older than 70 years, with metastasis or cancer, with concurrent shoulder disease such as infection, fracture and tumour, Non-cooperation of the patients, impaired consciousness in patients, severe cervical radiculopathy, therapeutic intervention by the persons not presenting in the plan, trauma during treatment, contraindication of corticosteroid injection.

Intervention groups

Patients with complete degenerative rotator cuff tear referring to the specialized clinic in Dezful city

Main outcome variables

pain_ Shoulder ROM

General information

Reason for update

Acronym

CSI

IRCT registration information

IRCT registration number: **IRCT20200102045987N1**

Registration date: **2020-03-03, 1398/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-03, 1398/12/13**

Update count: **0**

Registration date

2020-03-03, 1398/12/13

Registrant information

Name

Atousa Dacheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4264 0419

Email address

atousadacheh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the separate and combined effects of physiotherapy treatment and corticosteroid injection on range of motion and pain in patients with full thickness rotator cuff tear referring to the specialized clinic in Dezful city.

Public title

Examining the separate and combined effects of physiotherapy treatment and corticosteroid injection on range of motion and pain in patients with full thickness rotator cuff tear.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with degenerative rotator cuff tear confirmed by MRI and clinical examination. 30_70 years old No metastasis or cancer No concurrent shoulder disease like fracture and infection Patient collaborations and having informed consent No severe cervical radiculopathy Full consciousness No therapeutic intervention by the persons not presenting in the plan No trauma during treatment No contraindication of corticosteroid injection like sensitivity to these drugs and symptoms of skin infection at the injection site

Exclusion criteria:

Over than 70 years old Existence of Metastasis or cancer Existence of concurrent shoulder disease such as infection, fracture and tumor Non-cooperation of the patients Impaired consciousness in patients Existence of severe cervical radiculopathy Therapeutic intervention by the persons not presenting in the plan Trauma during treatment Contraindications of corticosteroid injection such as sensitivity to these drugs and symptoms of skin infection at the injection site Tears caused by acute trauma

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

96 patients are sampled in a randomized block method. They are divided into 3 groups of 33 individuals, as it were, all subset items are calculated based on the 6-

person blocks (AABBCC) and they are assigned to each Intervention groups according to the patients' random blocking.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of dezful University of Medical Sciences

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No.37, payervan Ave., Andimeshk Town

City

Andimeshk

Province

Khouzestan

Postal code

6484113532

Approval date

2019-12-28, 1398/10/07

Ethics committee reference number

IR.DUMS.REC.1398.045

Health conditions studied**1****Description of health condition studied**

Examining the separate and combined effects of physiotherapy treatment and corticosteroid injection on range of motion and pain in patients with full thickness rotator cuff tear

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain score of patients on the criterion VAS(Visual analogue scale)

Timepoint

The shoulder ROM in patients at the beginning of the study (before intervention) and at the end of physiotherapy sessions and one month after the last physiotherapy session

Method of measurement

Questionnaire DASH

2

Description

Shoulder Range of motion

Timepoint

The shoulder ROM in patients at the beginning of the study (before intervention) and at the end of physiotherapy sessions and one month after the last physiotherapy session

Method of measurement

Goniometr

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The shoulder ROM of 33 patients with rotator cuff tear is first measured by goniometer and DASH questionnaire will be completed by them; then, they will be put under 12 sessions of physiotherapy as massaging, exercises and stretching of rotator cuff and Scapular muscles, Strength exercises and modalities including TENS, Laser and US as twice a week for 6 weeks, each session lasting 45 minutes, including 30 minutes of electrotherapy and 15 minutes of manual therapy. At the end of the physiotherapy sessions, the DASH questionnaire is completed again by the patient and the motor function is checked with a goniometer, and is compared with the pre-intervention; in fact, the control and intervention groups are in common.

Category

Lifestyle

2

Description

Intervention group2: The shoulder ROM of 33 patients with rotator cuff tear is first measured by goniometer and DASH questionnaire will be completed by them; then, they are injected by 80 mg of methylprednisolone and 1 ml of 2% Lidocaine by an orthopaedic physician in two phases within 21 days and 3 weeks after the second injection, DASH questionnaire is completed by the patient and the motor function is checked with a goniometer; and is compared with the pre-intervention; in fact, the control and intervention groups are in common.

Category

Lifestyle

3

Description

Intervention group3: The shoulder ROM of 33 patients with rotator cuff tear is first measured by goniometer and DASH questionnaire will be completed by them; they

are injected by 80 mg of methylprednisolone and 1 ml of 2% Lidocaine and after 2 days, they will be put under 6 sessions of physiotherapy, twice a week for 3 weeks, each session lasts 45 minutes including 30 minutes of electrotherapy and 15 minutes of manual therapy by rehabilitation specialist and the second injection will be done again after 6 sessions of physiotherapy at the end of third week, and 6 sessions of physiotherapy will be done twice a week for 3 weeks, each session lasts 45 minutes (the physiotherapy steps are similar to the first group). At the end of the sessions, the DASH questionnaire is completed by the patient and the motor function is checked with a goniometer and is compared with the pre-intervention; in fact, the control and intervention groups are in common. At the end of the study, the data results before and after the intervention of these 3 groups will be compared.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinics

Full name of responsible person

Shaahin hajivandi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dezfoul University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Dezfoul 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

Dezfoul University of Medical Sciences

Full name of responsible person

Shaahin Hajivandi

Position

Academic staff of Dezful university of Medical sciences

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Latest degree

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Examining the separate and combined effects of physiotherapy treatment and corticosteroid injection on range of motion and pain in patients with complete rotator cuff tear referring to the specialized clinic in Dezful city.

When the data will become available and for how long

2021/3/21 to 2021/9/21

To whom data/document is available

Enthusiasts the subject under study

Under which criteria data/document could be used

In case of obtain written consent

From where data/document is obtainable

project managers

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

Send a written request letter to project managers

Comments