

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The effectiveness of dry needling with routine physiotherapy compared to routine physiotherapy on pain and range of motion in patients with rotator cuff repair surgery

#### Protocol summary

##### Study aim

Determining the effect of dry needle technique with routine physiotherapy treatment compared to routine physiotherapy treatment alone on pain, range of motion, shoulder girdle muscle strength and functional status of patients after rotator cuff repair surgery.

##### Design

randomized, double blinded, sham controlled trial with a parallel group of 52 patients.

##### Settings and conduct

The present study is in field of rotator cuff repair surgery rehabilitation that will be performed in Shafa Yahyaian hospital. Patients in the main group will receive range of motion and strengthening exercises, and shoulder joints mobilization techniques and electrical stimulation. in the main group, dry needle is inserted directly into the muscles that are involved with trigger points, and it will remain in place for 20 minutes. In the control group, patients will receive routine treatment, but will receive sham dry needle. In order to blind patients, the method of performing the technique will be exactly the same as the main group, but the dry needle is applied subcutaneously. for blinding, outcome assessments are performed by an examiner who is unaware of the groupings to which the patients belonged.

##### Participants/Inclusion and exclusion criteria

ages between 40 to 75 years rotator cuff repair surgery  
Passing at least 5 weeks after surgery and reporting shoulder pain patients who have trigger points in shoulder girdle muscles.

##### Intervention groups

Intervention group receives dry needle on the shoulder girdle muscles plus routine physiotherapy (electrotherapy, manual therapies, exercise therapy).  
Control group receives sham dry needle on the shoulder girdle muscles plus routine physiotherapy (electrotherapy, manual therapies, exercise therapy).

#### Main outcome variables

Resting pain Passive and active range of motion

#### General information

##### Reason for update

Change the expected sampling completion date Adding "shoulder pain" to the third paragraph of the inclusion criteria

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211005052677N1**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **prospective**

Last update: **2022-08-26, 1401/06/04**

Update count: **1**

##### Registration date

2022-02-19, 1400/11/30

##### Registrant information

###### Name

Faeze Naseri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 26 3460 7430

###### Email address

naseri.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-12-22, 1401/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of dry needling with routine physiotherapy compared to routine physiotherapy on pain and range of motion in patients with rotator cuff repair surgery

**Public title**

Effect of dry needling in the treatment of patients with rotator cuff repair surgery

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age range between 40 to 75 years Patients who have undergone rotator cuff repair surgery Patients who have passed at least 5 weeks since their surgery and they report shoulder pain Patients who have trigger points in shoulder girdle muscles palpation

**Exclusion criteria:**

Phobia of needle History of coagulation disorders and intake of anticoagulants History of head and neck surgery Radiculopathy and myelopathy disorders Pregnancy

**Age**

From **40 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

All eligible rotator cuff repair participants will be randomly assigned into routine physiotherapy plus dry needling (group 1) and routine physiotherapy plus sham dry needling (group 2) with an allocation ratio of 1:1. Randomization will be performed using variable blocks with 4 character blocks containing letters A, B. After randomizing, the randomization schedule will be transferred into written instructions and will be placed in sequentially numbered, opaque, and sealed envelopes (Letter A indicates dry needle plus routine physiotherapy and letter B indicates sham dry needle plus routine physiotherapy). The randomization process will be performed by someone who is outside the research team before the study begins. After the initial evaluation of the patients by the examiner, the numbered envelopes will be given to each patient according to the ordinal number of each person admitted to the study. Finally, after each

patient enters the treatment sessions, the therapist will adjust the treatment interventions based on the letters in the envelope. It should also be noted that after placing patients in the target group, they are asked not to provide their grouping information to the examiner to prevent data contamination.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients blinding: Before starting the study, patients are given enough information about their treatment and grouping. But after starting the study and grouping, patients do not know that they are in which of the main treatment group or control group. Outcome assessor blinding: The examiner who evaluates the outcomes before and after the intervention does not know the grouping of patients and does not know in which of the main treatment or control groups the patients being evaluated are.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical sciences

**Street address**

No. 16, ladan Dead end, East Akhtar, 45 Golshahr, Karaj3

**City**

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**Province**

Alborz

**Postal code**

3138716498

**Approval date**

2021-10-16, 1400/07/24

**Ethics committee reference number**

IR.IUMS.REC.1400.653

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

Rotator cuff repair surgery

**ICD-10 code**

M75.1

**ICD-10 code description**

Rotator cuff tear or rupture, not specified as traumatic

## Primary outcomes

### 1

#### **Description**

Resting pain

#### **Timepoint**

First session (before starting the intervention) and 10th session (after completing the intervention)

#### **Method of measurement**

Using the 0-100 Numeric Pain Rating Scale

### 2

#### **Description**

Active range of motion

#### **Timepoint**

First session (before starting the intervention) and 10th session (after completing the intervention)

#### **Method of measurement**

Using Goniometer

### 3

#### **Description**

Passive range of motion

#### **Timepoint**

First session (before starting the intervention) and 10th session (after completing the intervention)

#### **Method of measurement**

Using Goniometer

## Secondary outcomes

### 1

#### **Description**

Strength of shoulder girdle muscles

#### **Timepoint**

First session (before starting the intervention) and 10th session (after finishing the intervention)

#### **Method of measurement**

Using a manual dynamometer

### 2

#### **Description**

Functional status

#### **Timepoint**

First session (before starting the intervention) and 10th session (after finishing the intervention)

#### **Method of measurement**

Using the Shoulder Pain And Disability Index

## Intervention groups

### 1

#### **Description**

Intervention group: Patients in the intervention group after diagnosis of trigger points in the shoulder girdle muscles will receive Dry needling technique of the

shoulder girdle muscles (upper and middle and lower trapezius, Levator scapula, Rhomboid minor, Rhomboid major, Supraspinatus, Infraspinatus, Subscapularis, Teres Major, Teres Minor Deltoid) and conventional physiotherapy treatments that include electrical stimulation (Conventional TENS with a frequency of 120-180 Hz), manual therapies (mobilization of the Glenohumeral and Scapulothoracic joints), exercise therapy (exercises to increase the range of motion of the shoulder joints, strengthening exercises of the shoulder muscles). The number of treatment sessions for these patients is 10 in total, who receive 3 sessions of treatment per week every other day. . Patients receive conventional physiotherapy treatment in each session, but the dry needling technique will be performed in sessions 3, 5, 7, 9. In this study, myofascial trigger points will be identified by flat palpation of the taut bands between muscle fibers that produce referral pain or local twitch response. The method of performing the muscle needle technique will be based on the approaches proposed by Dommerholt and Fernandez de-las-Penas. After obtaining written consent from patients and preparing trigger points using alcohol-soaked cotton, a dry needle (acupuncture needle) is inserted directly into the muscles involved in the shoulder girdle in order to obtain local twitch response, and this will continue until no twitch response is obtained from the muscle. Finally, according to Hong's recommendation, the dry needle will remain in place for 20 minutes. An exercise training sheet will be given to the patients that explains home exercises. participants should perform home exercises 2 or 3 times a day for 4 weeks.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: In the control group, patients will receive routine physiotherapy treatment as in the main treatment group, which includes electrical stimulation (Conventional TENS with a frequency of 120-180), manual therapies (mobilization of the Glenohumeral and Scapulotorasic joints), exercise therapy (exercises to increase the range of motion of the shoulder joints, Shoulder muscle strength training). But instead of dry needling technique, they receive sham dry needle. In order to blind patients, the sham dry needling method is similar to the main method in all the steps, including how the patient is placed or how the technique is performed. The location of the trigger point in the patient is determined, then the patient is placed in the position that is the best way to perform dry needling of the target muscle, and after cleaning the area with alcohol-soaked cotton, the needle will insert subcutaneously, and then it remains in place for 20 minutes similar to the main dry needle method. In addition, the number of treatment sessions is similar to the main intervention group that is generally 10 sessions, which in sessions 3, 5, 7, 9 sham dry needling will be performed.

#### **Category**

Rehabilitation

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shafa Yahyaian hospital

**Full name of responsible person**

Faeze Naseri

**Street address**

Shafa Yahyaian hospital, Mojahedin Islam Street,  
Baharestan Square, Tehran

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Tehran

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PR@iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mehdi Dadgoo

**Street address**

Iran University of Medical Sciences School of  
Rehabilitation, Madadkaran Avenue, Shahnazari  
Street, Madar Square, Mirdamad, Tehran.

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**Email**

Dadgoo.m@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Faeze Naseri

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Mehdi Dadgoo

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Faculty member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

**Contact****Name of organization / entity**

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Faeze Naseri

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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faezenaseri94@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**

Undecided - It is not yet known if there will be 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**

Only main outcome measures will be shared.

**When the data will become available and for how long**

6 months after final reports

**To whom data/document is available**

Only academic researchers

**Under which criteria data/document could be used**

Only academic researchers

**From where data/document is obtainable**

To main investigator via email address

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

After receiving the request from the claimant and checking his eligibility, the response will be done via email after approximately one month.

**Comments**