Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 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 to75 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)

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+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
Karaj
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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran 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
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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Latest degree

Bachelor

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

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