

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effects of Eccentric Exercises accompany with and without Dry Needling Approches at the Patients with Chronic Rotator Cuff Tendinopathy

Protocol summary

Study aim

The purpose of adding a dry needle to eccentric exercises is to reduce the treatment time in the exercise program and achieve possible more effective treatment results and save time and money.

Design

Clinical trial with control group, with parallel group, single blinded, randomized based on random allocation rule, sample size= 40

Settings and conduct

1- Admission of patients with inclusion criteria 2- Dividing patients into two treatment groups 3- eight sessions of eccentric exercises and the other group, in addition to these exercises, is treated with a dry needle for 4 sessions. 4- At the beginning of the third session of the dry needle, the studied variables (except the questionnaires) are re-evaluated. 5- re-evaluate variables at the end 6 - At the end, after 72 hours, as fallow up, the said variables are re-evaluated to prevent the effect of dry needle Soreness on the evaluation results.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with positive diagnostic tests 2- aged 50 to 70 years 3- patients with chronic symptoms (3 to 6 months after the onset of symptoms) 4- Grade 1 and 2 tendon sprain Exclusion criteria: 1- Complete tendon rupture 2- Illiterate patients 3- Patients with cognitive problems 4- Patients with shoulder instability 5- History of cardiovascular disease

Intervention groups

The first group of patients receive dry needle treatment in addition to eccentric exercises. The patients of the second group are treated with eccentric exercises and dry needling as a placebo (in such a way that the needle sinks superficially and only to the patient's hypodermis) (control group).

Main outcome variables

Improves tendon injury and reduces pain; Save treatment time; Save on treatment costs; Low side

effects of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210112050016N1**

Registration date: **2021-02-02, 1399/11/14**

Registration timing: **prospective**

Last update: **2021-02-02, 1399/11/14**

Update count: **0**

Registration date

2021-02-02, 1399/11/14

Registrant information

Name

Shiva Pourshafie

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2296 3751

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Eccentric Exercises accompany with and without Dry Needling Approches at the Patients with Chronic Rotator Cuff Tendinopathy

Public title

dry needling and exercise therapy in rotator cuff tendinopathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with chronic rotator cuff tendinopathy that can approve with: X-Ray, MRI, US, doctor approval and exam tests(Neer Test and Hawkins-Kennedy Test) Age between 50 to 70 year Chronic diagnosis(at least 3 to 6 months after symptoms appearance) Tendon sprain in grade 1 or 2 in empty can test and lift off test

Exclusion criteria:

Patients whom have complete rupture of the rotator cuff muscle tendon Patients who are unable to read and write Patients who have cognitive problems and do not understand what is being asked of them Patients with instability (partial dislocation or dislocation) in the shoulder Patients with history of cardiovascular disease

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In base of random allocation rule, First, the number of sample size (40) is written on small and similar papers, then the papers are folded so that the numbers inside it are not known and placed inside the bag for drawing. Each patient randomly picks a piece of paper without replacement. Patients who pick up odd numbers are in the treatment group and patients who pick up even numbers are in the control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

patient in control group treat with eccentric exercise and placebo dry needling(needle will just go through the hypodermis)

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

No 15, east ladan, south golzar Ave. , sayad shirazi highway

City

Tehran

Province

Tehran

Postal code

1693939977

Approval date

2020-12-22, 1399/10/02

Ethics committee reference number

IR.TUMS.FNM.REC.1399.152

Health conditions studied

1

Description of health condition studied

Rotator cuff tendinopathy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain: Pain is an unpleasant sensation that is felt by an organism due to external or internal stimuli. There is usually no complete objective method for measuring pain, and most pain is assessed by mental methods. In this study, the amount of discomfort and pain in the shoulder and arm is measured by the VAS scale. Shoulder disability: Shoulder pain when resting or moving with limited mobility and function in the shoulder is referred to as disability. In this study, the amount of limitation and pain in movements and daily activities is measured with Quick DASH and SPADI scale and TFAST (Timed Functional Arm and Shoulder Test).

Timepoint

The beginning of the study, the third session of dry needle, the last session of treatment, 72 hours later

Method of measurement

VAS scale, quick DASH and SPADI questionnaire and TFAST functional test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: undergo eight sessions of eccentric exercises in such a way that in each session, three sets of abduction, internal rotation and external rotation exercises are performed eccentrically with 10 to 15 repetitions in each set; In addition, the exercises are treated with dry needles for 4 sessions in such a way that the dry needle is inserted in between sessions for patients.

Category

Treatment - Other

2

Description

Control group: 8 sessions of eccentric exercises and 4 sessions of dry needles as a placebo

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pishgam physiotherapy clinic

Full name of responsible person

Sharareh Zandi

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Dolat Street, between Qanat and Kaveh intersections,
Negin Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Siamak Bashardoust

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Enqelab St., Pich Shemiran, corner of Safi Alisha St.,
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Grant name

Grant code / Reference number

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

No

Title of funding source

Faculty of Rehabilitation of Tehran University of Medical
Science

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

Tehran University of Medical Sciences

Full name of responsible person

Siamak Bashardoust Tajali

Position

Assistant profossor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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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

No - There is not 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

Data included VAS scale, answers to Quick DASH and SPADI questionnaires and TFAST test and degree of shoulder abduction

When the data will become available and for how long

Until the publication of the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For approval in magazines

From where data/document is obtainable

Shiva Pourshafi and Dr. Siamak Bashardoost, Faculty of Rehabilitation, University of Tehran

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

Email to referrals

Comments