

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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)

##### Phone

+98 21 2296 3751

##### Email address

sh\_pourshafie@razi.tums.ac.ir

##### 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

##### Street address

Dolat Street, between Qanat and Kaveh intersections,  
Negin Complex

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##### Phone

+98 21 2259 4876

##### Email

shiva\_porshafie@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Siamak Bashardoust

##### Street address

Enqelab St., Pich Shemiran, corner of Safi Alisha St.,  
Faculty of Rehabilitation

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Tehran

##### Province

Tehran

##### Postal code

1148956111

##### Phone

+98 21 7753 5132

##### Email

s\_bashardoust@yahoo.com

##### 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

##### Street address

Enghelab St., Pich Shemiran, Faculty of Rehabilitation,  
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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Shiva Pourshafie

**Position**

Sudent

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

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**Full name of responsible person**

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**Position**

Student

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**Other areas of specialty/work**

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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**