

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of eccentric exercises on maximum grip strength, function, pain and thickness of common extensor tendon in patients with chronic lateral epicondylitis

#### Protocol summary

##### Study aim

Comparative examination of effect of eccentric exercises on maximum grip strength, function, pain and thickness of common extensor tendon in patients with chronic lateral epicondylitis.

##### Design

The study has a control group and is a randomized clinical trial, parallel and one-way blind.

##### Settings and conduct

In this study, patients will participate in two treatment groups for 6 weeks. Both groups receive routine physical therapy treatments during 12 treatment sessions twice a week in a physiotherapy center of the hospital and perform daily stretching exercises and ice massages at home. The treatment group also performs progressive eccentric strengthening exercises 3 times a day with 10-15 repetitions and at least 1-minute rest between each time. The assessor measures variables before and after the completion of the treatment period.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with chronic lateral epicondylitis. Abnormal appearance of the common extensor tendon in the ultrasound image. The average age is 55-35 years. Moderate pain; Exclusion criteria: Pain in the lateral epicondyle of the humerus due to involvement of the neck, shoulders and thorax. Acute inflammation. Trauma to the elbow. Patients with other specific problems in the upper extremities. Any surgical treatment, medication, topical injection and physiotherapy during the last 3 months.

##### Intervention groups

Both of control and treatment groups receive wrist extensor muscle stretching, ultrasound, massage friction, TENS anti analgesia during the session of physiotherapy treatment. In addition to the routine physiotherapy treatments, the treatment group performs progressive eccentric strengthening exercises.

##### Main outcome variables

Tendon thickness, Pain, Maximum hand grip strength, Function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180728040618N7**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **prospective**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

##### Registration date

2023-07-01, 1402/04/10

##### Registrant information

##### Name

Holakoo Mohsenifar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

mohsenifar.h@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-21, 1402/04/30

##### Expected recruitment end date

2023-10-22, 1402/07/30

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of eccentric exercises on maximum grip strength, function, pain and thickness of common extensor tendon in patients with chronic lateral epicondylitis

**Public title**

The effect of eccentric exercises on pain and function in patients with chronic lateral epicondylitis

**Purpose**

Treatment

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

Patients with chronic lateral epicondylitis (more than 3 months) Moderate pain based on the VAS scale (between 3-7) in the external epicondyle of the humerus, which increases with active wrist extension and decreases with rest Positive Mills test Positive Cozen test Positive Maudsley Existence of tenderness at the tenoperiosteal site or at the junction of the common extensor tendon to the external epicondyle of the humerus The average age is 55-35 years referred by a doctor

**Exclusion criteria:**

Pain in the lateral epicondyle of the humerus due to involvement of the neck, shoulders and thorax Acute lateral epicondylitis Pain in the lateral epicondyle of the humerus following a trauma to the elbow Radial tunnel syndrome and pain in the posterior interosseous nerve pathway Inflammation of the elbow joint Damage to the internal and external ligaments of the elbow joint Sensory disturbance in the involved limb Patients with bilateral symptoms or other specific problems in the upper extremities Neck problems Any surgical treatment, medication, topical injection and physiotherapy during the last 3 months Pregnancy Infection in the elbow joint Malignancy Hemophilia Dissatisfaction of participants in the study Patients with mental disorders or inability to communicate Patients who refuse to exercise

**Age**

From **35 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are randomly assigned to one of the two groups of usual passive physiotherapy and progressive eccentric strengthening exercises equally by the restricted randomization and law of random allocation (drawing a card from the number of cards equal to the sample size

and entering a group of two groups).

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

After placing the patients in the desired group, they are asked not to provide their grouping information to the examiner. All evaluations will be performed by a physical therapist. This person does not know about the grouping of patients with external epicondylitis of the elbow. In other words, during the initial and final evaluation of the patients, the examiner is not able to distinguish what type of treatment each patient received. Therapeutic interventions will be applied by another physiotherapist.

**Placebo**

Not 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

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Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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**Postal code**

1449614535

**Approval date**

2022-01-26, 1400/11/06

**Ethics committee reference number**

IR.IUMS.REC.1400.991

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

Chronic lateral epicondylitis

**ICD-10 code**

M77.1

**ICD-10 code description**

Lateral epicondylitis

**Primary outcomes****1****Description**

Tendon thickness

### **Timepoint**

Before the intervention and after the last treatment session

### **Method of measurement**

Ultrasonographic imaging

## **2**

### **Description**

Pain

### **Timepoint**

Before the intervention and after the last treatment session

### **Method of measurement**

Visual analog scale

## **3**

### **Description**

Maximum hand- grip strength

### **Timepoint**

Before the intervention and after the last treatment session

### **Method of measurement**

Digital hand held dynamometer

## **Secondary outcomes**

### **1**

#### **Description**

Function

#### **Timepoint**

Before the intervention and after the last treatment session

#### **Method of measurement**

The PREE questionnaire is used to measure performance. This questionnaire has 20 questions that examine two areas of pain and disability. The first field examines the degree of elbow pain in 5 questions. The maximum total score of this field is 50 (for each question, 0 pain-free state, and 10 maximum imaginable pain). The second field is related to disability, which measures a person's functional capacity during special activities (11 items) and usual activities (4 items). The maximum score of this domain is 50 (for each question, 0 is no limit, and 10 is the maximum difficulty to perform the activity). The final score of this questionnaire ranges from zero (the best score) to 100 (the worst score).

## **Intervention groups**

### **1**

#### **Description**

Control group: People receive stretching of the wrist extensor muscles, ultrasound, friction massage, and analgesic TENS during physiotherapy treatment. Stretching exercises for both groups are performed 2 times a day with 3 repetitions and 30 seconds rest between each repetition, in such a way that the person is standing and his shoulder is at a 90-degree flexion angle

and his elbow is at a 0-degree flexion angle and his palm is towards the ground and with the healthy hand, he takes his wrist to flexion and ulnar deviation and maintains the tension for 30 seconds. In this study, ultrasound with a frequency of 1 Mhz and an intensity of 1-1.5 W/Cm<sup>2</sup> is used. The circumference of the applicator head is four square centimeters, which is applied to the junction of the tendon of the extensor carpi radialis brevis muscle for 5 minutes. The modern pain-relieving TENS device is used with high frequency (110Hz) and intermittently in time intervals of 200  $\mu$ s and with an intensity that is strong for the patient and at the same time tolerable. Ice massage for the people of both groups is performed 3 times a day using an ice pack in the painful area of the external epicondyle in a circle for 5-10 minutes until this area becomes numb.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Intervention group: The treatment group performed progressive eccentric strengthening exercises while sitting in a straight position, while their elbows and wrists are in maximum extension and forearms are in pronation and supported by a surface, and the palms are facing the ground so that the wrists are used for performing movements. It hangs freely. The patient is asked to slowly bend the wrist for 30 counts and use the opposite hand to return it to the original position. This exercise is performed 3 times a day with 10 repetitions and at least 1-minute rest between each time. Before and after performing these exercises, wrist extensor muscles are stretched and finally, ice massage is performed on the external epicondyle of the humerus. Eccentric exercises are started at a low speed with or with weights according to the individual's condition, and the individual is told to continue the exercise if he has mild pain (pain less than 4 on the linear scale of pain), but if it worsens and becomes unbearable If pain occurs, stop the exercise. When the person will be able to do the exercise without any pain and discomfort, the exercise is done at a medium speed and with the same load, and again when the person does not feel pain and discomfort at this level, the exercise is done quickly. When the person is able to perform high-speed training without feeling pain and discomfort, the training load will be increased by using free weights based on the ten-repetition maximum of the patients. And during treatment, progress continues in this way. Eccentric exercises are taught to the patient in the first session of treatment, and corrections and improvements are made during weekly appointments for people to receive TENS and ultrasound treatment.

#### **Category**

Rehabilitation

## **Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

School of Rehabilitation Sciences of Iran University of Medical Sciences

**Full name of responsible person**

Holakoo Mohsenifar

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### Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

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**Full name of responsible person**

Hossein Keyvani

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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**

Holakoo Mohsenifar

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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**Position**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Deidentified individual participant data collected for the primary and secondary outcome measures will be shared if necessary

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

Starting 6 months after publication

**To whom data/document is available**

The data will be available for physical therapists working in academic institutions and also clinicians working in the field of musculoskeletal disorders

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

The raw data and results of this study can be used in future relevant systematic reviews. Thus, the raw data and results of this study will be available for researchers working in the field of lateral epicondylitis treatment and effects of eccentric exercises.

**From where data/document is obtainable**

Applicants can contact the researcher of this study Sahar Torkaman by email. Email address: shr\_torkaman@yahoo.com

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

Applicants should explain in detail about their project and how the data/documents of this study will be used in their project. Then, the data/documents files will be sent by email to applicants on request. This process may takes 10-12 working days.

**Comments**