

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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)

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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

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

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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 It 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/Cm² 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 μ 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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