Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of eccentric and concentric exercises in the treatment of lateral epicondylitis.

Protocol summary

Study aim
Determining the effect of eccentric and concentric exercises in the treatment of tennis elbow disease, Comparison of VAS pain level, DASH performance and grip strength between 3 groups, before starting the exercises and in the 4th and 8th week after starting the exercises.

Design
A clinical trial with three intervention groups, with parallel groups, single-blind, randomized, on 90 patients. The site kitset.ir is used for randomization.

Settings and conduct
This study is conducted on patients with a definitive diagnosis of lateral epicondylitis who are referred to Al-Zahra Hospital in Isfahan. These patients are divided into three groups of eccentric, concentric, and eccentric-concentric exercises and are treated for 4 weeks. Then, the effect of the exercises on the improvement of the disease is evaluated. In this study, blinding is performed on the evaluator, which is done by coding the patients and presenting the results to the evaluator without showing the assigned group.

Participants/Inclusion and exclusion criteria
inclusion criteria: definitive diagnosis of external epicondylitis by a specialist doctor and having symptoms for more than 3 months, age between 20 and 65 years, and patient consent. exclusion criteria: suffering from joint diseases and deformities, heavy and manual jobs, cervical radiculopathy and receiving other treatments except painkillers.

Intervention groups
There are three intervention groups in this study: eccentric exercise group, concentric exercise group, and eccentric-concentric exercise group. Exercises will be performed for 4 weeks in each group, and patients' pain and function will be assessed before starting the exercises, after completing the exercises, and 4 weeks after completing the exercises.

Main outcome variables
pain; performance; Grip strength

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241202063917N1**
Registration date: **2024-12-22, 1403/10/02**
Registration timing: **prospective**

Last update: **2024-12-22, 1403/10/02**
Update count: **0**

Registration date
2024-12-22, 1403/10/02

Registrant information
Name
Ali Dehghan marvast
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-01-03, 1403/10/14
Expected recruitment end date
2025-03-18, 1403/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date

empty

Scientific title
Evaluation of the effect of eccentric and concentric exercises in the treatment of lateral epicondylitis.

Public title
The effect of eccentric and concentric exercises in the treatment of lateral epicondylitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of lateral epicondylitis by a specialist doctor Having symptoms of lateral epicondylitis for more than 3 months Willingness and satisfaction of patients to perform regular exercise Age between 20 and 65 years Absence of inability to understand the scales used in the present study Ability to respond

Exclusion criteria:
Joint crepitus, instability, deformity or loss of motion and previous history of elbow fracture People with heavy and manual jobs (such as construction and industrial workers, heavy machinery operators, mechanics, construction painters, carpenters, etc.) Fibromyalgia, sprain, surgery or arthritis Neck radiculopathy Receiving treatments other than painkillers such as local steroid injection, physiotherapy, autologous blood injection, botulinum injection, etc.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The minimum total sample size was estimated to be 81 patients. Taking into account the probability of falling, a total of 90 samples are selected, which are randomly divided into three groups of 30 people using a lottery. For randomization, after coding each patient, we create a series of random numbers from 1 to 90 using kitset.ir. The first 30 numbers are assigned to group 1 (eccentric exercises), the second 30 numbers to group 2 (concentric exercises) and the third 30 numbers to group 3 (eccentric-concentric exercises).

Blinding (investigator's opinion)
Single blinded

Blinding description
For blinding, the person assessing the outcomes (eg, measuring pain, function and grip strength) will be unaware of patient grouping. This is done by coding the patients and presenting the results to the evaluator without showing the assigned group.

Placebo
Not used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Faculty of Medicine, Isfahan University of Medical Sciences and Health Services, Hezar Jarib Street

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2024-11-02, 1403/08/12

Ethics committee reference number
IR.MUI.MED.REC.1403.313

Health conditions studied

1

Description of health condition studied
Lateral epicondylitis

ICD-10 code
M77.1

ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Pain score in visual analog quality (VAS)

Timepoint
Pain assessment at the beginning of the study (zero week), the end of treatment (fourth week) and one month after treatment (eighth week)

Method of measurement
Visual analog quality (VAS)

2

Description
Upper limb function using the DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire

Timepoint
Pain assessment at the beginning of the study (zero

week), the end of treatment (fourth week) and one month after treatment (eighth week)

Method of measurement

DASH (Disabilities of the Arm, Shoulder, and Hand) questionnaire

3

Description

Measuring the patient's grip strength using Jamar's grip dynamometer

Timepoint

Measurement at the beginning of the study (week zero), the end of treatment (week four) and one month after treatment (week eight)

Method of measurement

Jamar grip dynamometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the eccentric exercise group, eccentric wrist extensor exercises are performed with the elbow on the bed in full extension, the forearm in pronation, the wrist in a stretched position (as high as possible), and the hand hanging over the edge. From this position, patients slowly bend their wrist while counting to 30 and return to the starting position with the help of the other hand. Exercises are performed in the form of 3 sets of 15 repetitions of slow progressive wrist extensor exercises in each treatment session with a 1-minute rest interval between each set.

Category

Treatment - Other

2

Description

Intervention group: In the concentric exercise group, the patient is seated with the elbow fully flexed (90 degrees), the forearm pronated, and the wrist in a neutral position. From this position, the patient slowly extends the wrist to maximum extension for a count of 30, using the opposite hand to return the wrist to flexion. Exercises are performed in the form of 3 sets of 15 repetitions of slow progressive wrist extensor exercises in each treatment session with a 1-minute rest interval between each set.

Category

Treatment - Other

3

Description

Intervention group: In the eccentric-concentric exercise group, the elbow is in full extension on the bed, the forearm is in pronation, the wrist is extended (as high as possible), and the hand is hanging over the edge of the bed. From this position, patients slowly flex their wrist while counting to 30, then return to the starting position (stretch). Exercises are performed in the form of 3 sets of 15 repetitions of slow progressive wrist extensor exercises in each treatment session with a 1-minute rest interval between each set.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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
Esfahan 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
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Ali Dehghan Marvast
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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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 on the study's three primary outcomes, pain, function, and grip strength, can be shared after de-identifying subjects.
When the data will become available and for how long
Access starts 6 months after results are published

To whom data/document is available

The data will be accessible to all people who want to use the data, including researchers, students, doctors, etc.

Under which criteria data/document could be used

The data can be used for review articles provided the source is mentioned.

From where data/document is obtainable

Applicants can send their application through the email of the authors of the article.

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

After sending the request by the applicant, the request will be raised with other writers and if they agree, the data will be sent to the applicant. This process will take about a week.

Comments