Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation and Comparison of the Effectiveness of Corticosteroid Injection and Electroacupuncture in Controlling Pain and Improving Performance in Patients with Lateral Epicondylitis (Tennis Elbow)

Protocol summary

Study aim

Main Goal: Compare the effectiveness of corticosteroid injection vs. electroacupuncture in managing pain and function in tennis elbow patients. Secondary Goals: Measure pain and function changes before and after treatment (3 and 6 months) using VAS and PRTEE. Compare outcomes between the two treatment groups. Practical Goal: Identify the more effective method to improve patient care and update clinical guidelines.

Design

Participants will be randomly assigned to one of two groups: the corticosteroid group or the electroacupuncture group. The required sample size is 22 participants per group, totaling 44 participants in the study.

Settings and conduct

This study will be a single-blind, parallel-group RCT with two treatment arms The trial will be conducted at Firouzgar Hospital, Shafa Yahyaian Hospital, and Rasoul Akram Hospital.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adults aged between 18 and 65 years. Clinically diagnosed with lateral epicondylitis (tennis elbow) for at least 6 weeks. Experiencing pain that has not responded to conservative treatments such as rest or physiotherapy. A baseline pain score of ≥ 4 on the Visual Analogue Scale (VAS). Ability to provide informed consent. Exclusion Criteria: History of corticosteroid injection or electroacupuncture for lateral epicondylitis within the past 6 months. Presence of systemic inflammatory conditions (e.g., rheumatoid arthritis). History of elbow surgery. Pregnant or breastfeeding women. Patients receiving anticoagulant therapy or with known bleeding disorders.

Intervention groups

Participants will be randomly assigned to one of two treatment groups: 1. Corticosteroid Injection Group 2. Electroacupuncture Group

Main outcome variables

Pain reduction and improvement of quality of life in patients with tennis elbow.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191002044951N2**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

Koorosh Mansoori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8214 1229

Email address

mansoori.k@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-23, 1404/03/02

Expected recruitment end date

2025-11-23, 1404/09/02

Actual recruitment start date

2025-05-25, 1404/03/04

Actual recruitment end date

2025-12-25, 1404/10/04

Trial completion date

2026-03-21, 1405/01/01

Scientific title

Evaluation and Comparison of the Effectiveness of Corticosteroid Injection and Electroacupuncture in Controlling Pain and Improving Performance in Patients with Lateral Epicondylitis (Tennis Elbow)

Public title

Evaluation and Comparison of the Effectiveness of Corticosteroid Injection and Electroacupuncture in Controlling Pain and Improving Performance in Patients with Lateral Epicondylitis (Tennis Elbow)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults aged between 18 and 65 years Clinically diagnosed with lateral epicondylitis (tennis elbow) for at least 6 weeks. Experiencing pain that has not responded to conservative treatments (e.g., rest, physiotherapy). the Visual Analog Scale ≥ 4 (VAS; 0–10) at baseline. Ability to provide informed consent.

Exclusion criteria:

Occurrence of serious adverse events resulting from therapeutic interventions (such as infection, severe reaction to injection, or electroacupuncture). Non-compliance with post-treatment instructions:a) In the injection group: engaging in intense physical activities during the restricted period after injection.b) In the electroacupuncture group: failure to follow recommendations regarding rest or proper use of the treated limb. Lack of patient cooperation in continuing treatment sessions or scheduled evaluations. Emergence of new medical conditions that may affect the study outcomes (e.g., surgery or acute illnesses). Patient’s decision to withdraw from the study at any time, even after signing the informed consent. Investigator’s judgment that continued participation may pose a risk to the patient’s health.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **44**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

1. Randomization: In this study, participants will be allocated into two treatment groups using a restricted randomization method. To ensure balance in the number of individuals in each group, blocks of equal size will be used. Given a sample size of 44 participants, 11 blocks of 4 individuals each will be designed. Each block will include two participants assigned to the corticosteroid group and two to the electroacupuncture group. The allocation order within each block will be determined randomly using a random number generator software. These combinations will be written on identical pieces of paper, each placed inside an opaque envelope. The envelopes will be organized sequentially within each block. When a patient visits the clinic, they will be asked to randomly select one envelope. The number inside the envelope will determine the patient’s treatment group and will be recorded on designated forms. Preparation of the Randomization List: A randomization list containing various group combinations for each block (e.g., 1-2-2-1) will be generated using the random number generation feature of SPSS software. This list will be provided to the principal investigator and will be used to assign patients to the groups. Preparation of the Envelopes: Papers of equal size will be prepared, each labeled with the numbers “1” (corticosteroid) or “2” (electroacupuncture). Each block will contain a combination of numbers according to the randomization list. The papers will be individually placed in opaque, identical envelopes. These envelopes will be numbered sequentially and organized according to their corresponding blocks. Assignment of Patients to Groups: When a participant visits the clinic, they will randomly select an envelope from the relevant block. The number inside the envelope will indicate the treatment group (1 or 2) to which the patient is assigned. The researcher will record the allocation code, and the remaining envelopes in the block will be stored until the block is fully used.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding of Assessors and Data Analysts: Assessors: Outcome assessors (e.g., for VAS and PRTEE questionnaires) will be blinded to the treatment group allocation. To ensure this, participant files will be coded anonymously as either “A” or “B”. Data Analyst: The final data will be reviewed and analyzed by a data analyst who will also be blinded to the treatment groups and will only work with the anonymous codes (“A” and “B”). Bias Control: All interactions with participants will be handled by the treatment team, and assessments will be conducted in a separate room by independent, neutral personnel. Data will be encoded separately, and only the principal investigator will have access to the encryption key.

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 Hemmat Highway, near Milad Tower, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2025-04-01, 1404/01/12

Ethics committee reference number
IR.IUMS.FMD.REC.1404.011

Health conditions studied

1

Description of health condition studied
Lateral epicodylitis

ICD-10 code
M77.1

ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Pain according to VAS score and PRTEE

Timepoint
The outcomes are assessed at three time points: at baseline, 3 months, and 6 months after the intervention.

Method of measurement
VAS score and PRTEE

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Corticosteroid Injection Group (Group 1):Participants in this group will receive a single corticosteroid injection. The corticosteroid used will be triamcinolone acetonide, a long-acting agent commonly used in the treatment of inflammatory conditions. A dose of 1 mL (40 mg/mL) will be prepared.The injection will be administered at the point of maximal tenderness over the lateral epicondyle, as determined by palpation. The patient will be positioned comfortably with the elbow slightly flexed and supported during the procedure.

Category
Treatment - Other

2

Description
Intervention group: Electroacupuncture Group (Group 2):Participants in this group will undergo six sessions of electroacupuncture over a three-week period, with treatments administered twice per week.Sterile, single-use acupuncture needles (0.25 mm in diameter and 40 mm in length) will be used to ensure patient safety and reduce the risk of infection.Needles will be inserted bilaterally at predetermined acupuncture points around the lateral epicondyle. Common points include Quchi (LI11), Shousanli (LI10), and Ashi points (tender points identified by palpation). Electroacupuncture Details:An electroacupuncture device will be connected to pairs of needles to deliver a low-frequency electrical current (2–4 Hz).The intensity of the electrical stimulation will be adjusted according to the patient’s tolerance, producing sensations ranging from mild tingling to slight muscle contractions.Each session will last for 30 minutes, during which the patient will remain in a resting position.Treatment will be administered twice per week for a total of three weeks, resulting in six sessions overall.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
Romina karimi

Street address
Firoozgar Hospital, Beh Afarin Street, Karim Khan Zand Boulevard, Valiasr Square, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1593747811

Phone
+98 21 8214 1000

Fax
+98 21 8214 1000

Email
firoozgarhospital1@gmail.com

Web page address
https://firoozgar.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Majid safa
Street address
Iran University of Medical Sciences (IUMS)/Hemmat highway
City
Tehran
Province
Tehran
Postal code
Phone
+98 21 8670 1021
Fax
+98 21 8805 2248
Email
info@iums.ac.ir
Web page address
http://iums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Kourosh Mansory
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Baharestan square
City
Tehran
Province
Tehran
Postal code
14597943644
Phone
+98 912 375 2812
Email
Mansoori.k@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Romina karimi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
Beh Afarin St , Valiasr Square., Firozgar Hospital
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1000
Email
Rominakarimi1374@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Kourosh Mansory
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Baharestan square
City
Tehran
Province
Tehran
Postal code
14597943644
Phone
+98 912 146 7966
Email
Mansoori.k@iums.ac.ir

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

No - There is not 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

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be delivered to the research center in the form of an Excel file.

When the data will become available and for how long

The access period begins six months after the publication of the results.

To whom data/document is available

It will be available to researchers affiliated with academic and scientific institutions.

Under which criteria data/document could be used

No decision has been made yet

From where data/document is obtainable

Data Availability and Contact Information: For further information, access to the data, or details regarding the analyses, please contact the study coordinator: Name: Dr. Kourosh Mansoori Phone Number: +98 912 146 7966 Institutional Address: Shafa Yahyaian Hospital Email: Mansoori.k@iums.ac.ir

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

The requester of the documents can correspond with the author of the articles and send her request through the contact number or email registered in the previous section and receive the information in less than one working week and also state the purpose of receiving the data.(feminine) The requester of the documents can correspond with the author of the articles and send his request through the contact number or email registered in the previous section and receive the information in less than one working week and also state the purpose of receiving the data

Comments