

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effects of TECAR on pain, functional disability, and extensor carpi radialis brevis muscle thickness in patients with lateral epicondylitis A randomized controlled trial

Protocol summary

Study aim

To compare the effects of "Transfer of Energy Capacitive and Resistive " therapy in addition to routine physiotherapy on pain intensity, functional performance, and extensor carpi radialis brevis muscle thickness in patients with lateral epicondylitis.

Design

A concealed, randomized, blinded, clinical trial with 22 patients

Settings and conduct

Patients refer to the physiotherapy clinic of Dr. Heshmat Hospital based on the diagnosis of an orthopedic surgeon. After obtaining informed consent, all samples participate in a pre-test to examine the research variables. Finally, patients are randomly divided into 2 groups: control and intervention using a block randomization method. Patients and the evaluator are unaware of the group assignment. Blinding will be done with a transparent envelope. Both groups receive physiotherapy 3 times a week for 10 sessions according to their treatment protocol. All groups receive general physiotherapy including an electrical stimulation device and exercise therapy. The study group receives real deep heat and control group receive sham deep heat. At the end, the research variables are re-evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Patients over 20 years with tennis elbow syndrome diagnosed by an orthopedic surgeon 2- Positive Cosen test Exclusion criteria: Injection in the affected area and cervical radiculopathy

Intervention groups

Control group: Routine physiotherapy and exercise therapy (exercise and stretching program based on impairment, manual therapy based on impairment using Mulligan technique, deep transverse friction massage) and deep heat (sham) Intervention group: In addition to routine physiotherapy, 900 kHz frequency and

capacitance mode deep heat therapy will be used for ten sessions.

Main outcome variables

Pain intensity, functional disability, and extensor carpi radialis brevis muscle thickness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211030052912N6**

Registration date: **2026-06-16, 1405/03/26**

Registration timing: **prospective**

Last update: **2026-06-16, 1405/03/26**

Update count: **0**

Registration date

2026-06-16, 1405/03/26

Registrant information

Name

Somaye Azarnia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 7173 2824

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-01, 1405/05/10

Expected recruitment end date

2026-09-01, 1405/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of TECAR on pain, functional disability, and extensor carpi radialis brevis muscle thickness in patients with lateral epicondylitis A randomized controlled trial

Public title

Effects of TECAR in Tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient over the age of 20 diagnosed with Tennis elbow Pain and Tenderness around the lateral epicondyle that gets worse with active extension of the hand wrist Positive Kozen's test

Exclusion criteria:

Tumor or infectious cause of elbow pain Corticosteroid injection within the previous 3 months. Greater than 50% tear of the common extensor tendon, as assessed by ultrasonography. Previous autologous blood or platelet-rich plasma (PRP) injection Hemorrhagic diathesis or current anticoagulant therapy. Local infection. History of elbow surgery or fracture Inflammatory arthritis or osteoarthritis of the elbow Cervical radiculopathy Pregnancy or planning to become pregnant during the study period Inability to complete questionnaires Inability to provide informed consent due to a mental health disorder.

Age

From **20 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

After the initial evaluations, patients will be allocated to either the intervention or control group using block randomization. Randomization will be conducted via Randomization.com. Considering the two groups (intervention A and control B), six blocks of four participants each will be generated. Each allocation sequence will be documented on a card and placed in a sealed envelope. As participants are enrolled, the envelopes will be opened sequentially to reveal the group assignment. This study is double-blind: both the participants and the outcome assessor will remain

unaware of group allocation. Randomization and outcome assessment will be performed by an individual who is not involved in the treatment of the patients, ensuring that the assessor is blinded to the intervention type.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, patients and the evaluator are unaware of the type of group assigned. Randomization and intervention will be performed by a person who is not involved in the patient assessment process, and the evaluator is also unaware of the type of intervention. Patients in both groups receive the same treatment. The intervention group receives real treatment and the control group receives sham. The intervention is performed for all patients in the same location and in the morning shift.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Guilan university of medical sciences

Street address

Heshmat Crossroads, Dr. Heshmat Hospital

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Rasht

Province

Guilan

Postal code

419395588

Approval date

2026-05-20, 1405/02/30

Ethics committee reference number

IR.GUMS.REC.1405.084

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

tennis elbow

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

Primary outcomes

1

Description

Pain intensity

Timepoint

Before the first session and after the final intervention session (session 10).

Method of measurement

In this study, pain intensity will be assessed using the Visual Analog Scal

2

Description

Functional disability

Timepoint

Before the first session and after the final intervention session (session 10).

Method of measurement

"Patient- Rated Tennis Elbow Evaluation" questionnaire

3

Description

Extensor carpi radialis brevis muscle thickness

Timepoint

Before the first session, and after the final intervention session (session 10).

Method of measurement

sonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine physiotherapy and exercise therapy and impulse therapy will be used. Impedance mode impulse therapy, 900 kHz frequency will be used on the affected points with the aim of vascularization, three times a week for ten sessions. The training includes: a disorder-based exercise and stretching program and disorder-based manual therapy.

Category

Rehabilitation

2

Description

Control group: Routine physiotherapy and exercise therapy will be used three times a week for ten sessions. Exercise includes: a disorder-based exercise and stretching program and disorder-based manual therapy.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat hospital

Full name of responsible person

Somayye Azarnia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht 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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Somaye Azarnia

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No further information available.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available