

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing the Effects of TECAR and DN Added to Routine Physical Therapy on Elbow Pain and Function in Patients with Tennis Elbow Syndrome: 3 group randomized controlled trial

#### Protocol summary

##### Study aim

Comparison of the effects of TECAR therapy and dry needling, in addition to routine physiotherapy, on pain intensity and elbow function in patients with lateral epicondylitis (tennis elbow).

##### Design

A randomized, double-blind, parallel-group, controlled clinical trial will be conducted on 40 patients.

##### Settings and conduct

In this study, patients with lateral epicondylitis (tennis elbow) referred by an orthopedic specialist to the physiotherapy clinic of Dr. Heshmat Teaching Hospital will be selected based on the inclusion criteria and then randomly allocated to three groups (control, experimental 1, and experimental 2) using block randomization, where each group will receive its corresponding intervention.

##### Participants/Inclusion and exclusion criteria

Patients aged over 20 years with a diagnosis of lateral epicondylitis presenting with lateral elbow pain and tenderness aggravated by active wrist extension and a positive Cozen's test will be included, while those with local injection at the affected site, diabetes or hemophilia, pregnancy, or physician-confirmed peripheral nerve entrapment or cervical radiculopathy will be excluded.

##### Intervention groups

Experimental Group 1 will receive routine physiotherapy plus TECAR therapy (capacitive mode, 480 kHz) for 10 sessions, while Experimental Group 2 will receive routine physiotherapy plus dry needling every other session (5 sessions in total) over 10 sessions.

##### Main outcome variables

Pain intensity and functional disability.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211030052912N4**

Registration date: **2026-06-01, 1405/03/11**

Registration timing: **prospective**

Last update: **2026-06-01, 1405/03/11**

Update count: **0**

##### Registration date

2026-06-01, 1405/03/11

##### Registrant information

##### Name

Somaye Azarnia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7173 2824

##### Email address

azarnia.pt.82@gmail.com

##### Recruitment status

**Not yet recruiting**

##### 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

Comparing the Effects of TECAR and DN Added to Routine Physical Therapy on Elbow Pain and Function in Patients with Tennis Elbow Syndrome: 3 group randomized controlled trial

## Public title

Comparison of the effects of TECAR therapy and dry needling in patients with lateral epicondylitis (tennis elbow).

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients aged over 20 years with a diagnosis of lateral epicondylitis (tennis elbow) 2. Presence of pain and tenderness around the lateral epicondyle that is aggravated by active wrist extension. 3. A positive Cozen's test.

### Exclusion criteria:

1. Injection in the affected area. 2. Diabetes or hemophilia. 3. Pregnancy 4. Peripheral nerve entrapment or cervical radiculopathy confirmed by a physician.

## Age

From 20 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

After initial evaluations, patients will be randomly assigned to three groups (control, experimental 1, and experimental 2) using block randomization.

Randomization will be performed via the website [www.sealedenvelope.com](http://www.sealedenvelope.com). In this method, five blocks of six participants will be generated for the three study groups. Each allocation sequence will be recorded on a card and placed inside an envelope. As patients are enrolled, the envelopes will be opened sequentially, and the assigned group for each participant will be determined. This is a double-blind study in which both the participants and the outcome assessor will be unaware of group allocation.

Randomization and outcome assessment will be conducted by an individual who is not involved in the treatment process, and the assessor will also be blinded to the type of intervention.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this double-blind study, both the participants and the outcome assessor will be unaware of the assigned group. Randomization and intervention will be performed by an individual who is not involved in the outcome

assessment, and the assessor will remain blinded to the type of intervention.

## 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

##### City

Rasht

##### Province

Guilan

##### Postal code

4193955588

#### Approval date

2026-05-20, 1405/02/30

#### Ethics committee reference number

IR.GUMS.REC.1405.082

## 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 and after 10 sessions.

#### Method of measurement

VAS Questionnaire

### 2

#### Description

functional disability

#### Timepoint

Before and after 10 sessions.

#### Method of measurement

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Experimental Group 1: In addition to routine physiotherapy, TECAR therapy in capacitive mode at 480 kHz will be applied for 10 sessions.

#### Category

Treatment - Devices

### 2

#### Description

Experimental Group 2: In addition to routine physiotherapy, dry needling will be performed every other session (a total of 5 sessions over the 10-session treatment period).

#### Category

Treatment - Devices

### 3

#### Description

Control Group: Participants will receive routine physiotherapy, including:\* Hot pack + TENS for 15 minutes\* Ultrasound at 1.5 W/cm<sup>2</sup>, 1 MHz frequency, 20% duty cycle for 5 minutes\* Therapeutic exercises (strengthening and stretching of the ECRB muscle and transverse friction massage) if the patient is pain-free during daily activities.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

بیمارستان دکتر حشمت در رشت

##### Full name of responsible person

Somayye Azarnia

##### Street address

Heshmat Crossroads, Dr. Heshmat Hospital

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##### Phone

+98 13 3366 9064

##### Email

heshmat@gums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Rasht University of Medical Sciences

##### Full name of responsible person

Dr. ali alavi

##### Street address

Opposite 17 Shahrivar Hospital, Shahid Siyadati Street, Namjoo Street, Rasht

##### City

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##### Province

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##### Postal code

41446-66949

##### Phone

+98 13 3233 5821

##### Email

research@gums.ac.ir

#### 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

Assitant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Physiotherapy

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Position**

Assistant Professor

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Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

Statistical charts and data tables

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

Access period begins 5 months after publication.

**To whom data/document is available**

Scientific researchers

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

There is no prohibition on submitting data for the purpose of conducting scientific research and citing the source.

**From where data/document is obtainable**

send email

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

about 1 week

**Comments**