Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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
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. 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

PRTEE Questionnaire

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/cm², 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
City
Rasht
Province
Guilan
Postal code
4193955588
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
Rasht
Province
Guilan
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
Street address
Guilan University of Medical Sciences' Headquarters, Parastar St., Rasht
City
Rasht
Province
Guilan
Postal code

4193955588

Phone
+98 13 3366 9064

Email
azarnia.pt.82@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Azarnia Somaye

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
No .10, Shahid Nazari Ave, Shahid Beheshti Blvd., Rasht

City
Rasht

Province
Guilan

Postal code
41939555588

Phone
+98 13 3366 9064

Email
azarnia.pt.82@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences

Full name of responsible person
Azarnia Somaye

Position
Assisstant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

Street address
No .10, Shahid Nazari Ave, Shahid Beheshti Blvd., Rasht

City
Rasht

Province
Guilan

Postal code
4193955588

Phone
+98 13 3366 9064

Email
azarnia.pt.82@gmail.com

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