

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of TECAR therapy on the improvement of symptoms and function of patients with lateral epicondylitis

Protocol summary

Study aim

Determining of TECAR therapy on the improvement of symptoms and function of patients with lateral epicondylitis

Design

The randomized, Single-blind clinical trial, with the parallel groups, Phase 3 on 46 patients

Settings and conduct

In this randomized Single-blind clinical trial study, 46 eligible patients referred to physical medicine and rehabilitation clinic of Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into two groups. Patients in the first group will be prescribed meloxicam and TECAR therapy and the second group will be given only meloxicam. Then their pain scores and performance will be compared between the two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include diagnosis of lateral epicondylitis, lateral epicondylitis pain that lasts for at least 1 month, age category 18-65 years, and satisfaction to participate in the study. Exclusion criteria include having history of inflammatory joint disease, having history of affected elbow surgery, injection or physiotherapy of the affected elbow in the last 6 months, having history of trauma and elbow injury, existence of diseases that mimic the symptoms of lateral epicondylitis, and contraindications to TECAR device (pregnancy, pacemaker, insulin pump, hearing aid, thrombophlebitis, growth plate, cancer, open wounds and skin lesions, skin allergies, fever and infection, lack of heat and heart disease).

Intervention groups

Intervention group: Patients in this group undergo TECAR therapy for 5 sessions, 3 days a week. In addition, meloxicam 15 mg is prescribed for two weeks. The use of brace (Cock-up) is also prescribed during treatment. Control group: For patients in this group, meloxicam 15 mg is prescribed for two weeks. The use of brace (Cock-up) is also prescribed during treatment.

Main outcome variables

Pain scores; Performance of arm, shoulder and hand (DASH)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220115053718N1**

Registration date: **2022-01-21, 1400/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-21, 1400/11/01**

Update count: **0**

Registration date

2022-01-21, 1400/11/01

Registrant information

Name

Sahar Arzaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3833 5910

Email address

sahar.arzaghi@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-21, 1400/11/01

Expected recruitment end date

2022-08-21, 1401/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of TECAR therapy on the improvement of symptoms and function of patients with lateral epicondylitis

Public title
Effect of TECAR therapy on the improvement of symptoms and function of patients with lateral epicondylitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis of lateral epicondylitis by a physical medicine and rehabilitation specialist with physical examination
 Lateral epicondylitis pain that lasts for at least 1 month
 Age category 18-65 years
 Satisfaction to participate in the study
Exclusion criteria:
 Having history of inflammatory joint disease
 Having history of affected elbow surgery, injection or physiotherapy of the affected elbow in the last 6 months
 Having history of trauma and elbow injury
 Existence of diseases that mimic the symptoms of lateral epicondylitis
 Contraindications to pregnancy (pregnancy, pacemaker, insulin pump, hearing aid, thrombophlebitis, growth plate, cancer, open wounds and skin lesions, skin allergies, fever and infection, lack of heart and heart disease)

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

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 46 eligible patients are randomly selected. For this, the letter A is written on 23 sheets, and the letter B is written on 23 sheets, and each of them is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the different nature of the intervention in the two groups, the researcher and the patient are aware of the type of intervention, but the outcome assessor, data collector and statistical analyst will not be aware of the

type of intervention.

Placebo
Not used

Assignment
Parallel

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
 Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
 Isfahan
Province
 Isfahan
Postal code
 8179964167
Approval date
 2021-12-24, 1400/10/03
Ethics committee reference number
 IR.MUI.MED.REC.1400.705

Health conditions studied

1

Description of health condition studied
Lateral epicondylitis

ICD-10 code
M77.0

ICD-10 code description
Medial epicondylitis

Primary outcomes

1

Description
Pain

Timepoint
Before treatment, immediately and 1 month after the end of treatment

Method of measurement
Visual Analogue Scale(VAS)

2

Description
The Disabilities of arm, shoulder and hand Score

Timepoint
Before treatment, immediately and 1 month after the

end of treatment
Method of measurement
The Disabilities of the Arm, Shoulder and Hand
questionnaire(DASH)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group undergo TECAR therapy for 5 sessions, 3 days a week (every other day for 2 weeks). In addition, meloxicam 15 mg is prescribed for two weeks. The use of brace (Cock-up) is also prescribed during treatment.

Category

Treatment - Devices

2

Description

Control group: For patients in this group, meloxicam 15 mg is prescribed for two weeks. The use of brace (Cock-up) is also prescribed during treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Parisa Taheri

Street address

Soffe Blvd, Isfahan

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8174675731

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Prs_taheri@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Parisa Taheri

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Al-Zahra Hospital, Department of Physical Medicine
and Rehabilitation

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Province

Isfahan

Postal code

8174675731

Phone

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Email

Prs_taheri@yahoo.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

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Esfahan University of Medical Sciences

Full name of responsible person

Parisa Taheri

Position

Non-faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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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

There is no further information

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

No - There is not 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