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 devise(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)
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+98 71 3833 5910
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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 heat 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

Isfehan

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

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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

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Person responsible for scientific

inquiries

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Esfahan University of Medical Sciences

Full name of responsible person
Parisa Taheri

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
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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