

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of pulse and continuous ultrasound therapy on pain and function of patients with lateral epicondylitis

Protocol summary

Summary

In this triple blind (patient, therapist, assessor), clinical randomized trial (phase 3) we aim to investigate the effect of 10 sessions of continuous and pulsed ultrasound application in comparison to sham ultrasound (on device without output). Subjects suffering from lateral epicondylitis for more than 3 months (60 patients from one university hospital), aged between 18 and 65, will be randomly allocated to 3 groups using sealed envelopes. All groups will receive ultrasound (real or sham; continuous ultrasound: 3 MHz, 1 watt/cm², pulse ultrasound: 3 MHz, 1.7 watt/cm²) 3 days per week plus specific stretching and strengthening exercises. Pain (using visual analogue scale) and upper extremity function (using Quick DASH (Disabilities of the Arm Shoulder and Hand) questionnaire) will be measured before and after treatment as well as in 2 months follow up.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020121139N3**

Registration date: **2016-05-18, 1395/02/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-18, 1395/02/29

Registrant information

Name

Safoora Ebadi

Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-11-21, 1395/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pulse and continuous ultrasound therapy on pain and function of patients with lateral epicondylitis

Public title

The effect of ultrasound waves on Tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1. Having lateral epicondylitis for more than 3 months 2. No history of surgery or fracture in upper extremity or spine 3. Not having any systemic disease 4. Have not received physiotherapy treatment of any kind during last 6 months 5. Not pregnant 6. Not having psychological problems or not using any medicine related to psychological problems Exclusion Criteria: 1. Patient not willing to continue treatment 2. Violation of any one of inclusion criteria

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran, IRAN

City

Tehran

Postal code

Approval date

2015-12-04, 1394/09/13

Ethics committee reference number

IR.IUMS.REC 1394.8611215627

Health conditions studied

1

Description of health condition studied

Lateral epicondylitis

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis or Tennis elbow

Primary outcomes

1

Description

Pain

Timepoint

before treatment-after 10 sessions of treatment- in 2 months followup

Method of measurement

visual analog scale

Secondary outcomes

1

Description

function

Timepoint

before treatment -after 10 sessions of treatment- in 2months followup

Method of measurement

Disability of arm shoulder and hand questionnaire

Intervention groups

1

Description

first group continuous ultrasound 3 mega hertz 1.5 watt/cm2 3minutes

Category

Rehabilitation

2

Description

second group: pulsed ultrasound duty cycle 70% 2 watt/cm2 3 minutes

Category

Rehabilitation

3

Description

control group: sham ultrasound (on device with zero out put) applied over the affected area for 3 minutes

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firouzgar Hospital

Full name of responsible person

Dr. Safoora Ebadi

Street address

Physical Medicine and Rehabilitation Department, Firouzgar Hospital, Behafarin St., Karim khane zand St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Iran University of Medical Sciences

Full name of responsible person

Dr. Javad Ali Musavi

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Iran University of Medical Sciences ,Shahid Hemmat Highway .Tehran,1449614535,IRAN

City

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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

Vice chancellor for research, Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Iran University of Medical Sciences; Faculty of Medicine

Full name of responsible person

Dr. Safoora Ebadi

Position

Assistant Professor

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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty