Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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/cm 2, pulse ultrasound: 3 MHZ, 1.7 watt/cm 2) 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

Iran (Islamic Republic of)

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+98 912 175 7107

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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

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

City
Tehran

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

Other areas of specialty/work

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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