

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between ultrasound therapy and biofeedback therapy in treatment of lateral epicondylitis

Protocol summary

Study aim

Efficacy of electromyography and ultrasound biofeedback in the treatment of lateral epicondylitis

Design

This study is a phase 3 clinical trial in which 50 patients undergo rehabilitation in two independent groups of biofeedback and ultrasound. Randomization is done using envelopes seals and is done in a single blind manner. The person who measures the outcome of the intervention is not aware of the type of intervention.

Settings and conduct

This study was conducted in the physical and rehabilitation ward of Besat Hospital in Hamadan. The target group is patients with lateral epicondylitis who undergo biofeedback and ultrasound rehabilitation because of the severity of pain and disability and failure to respond to the Non-steroidal and anti-inflammatory drugs. this study, is single blind. The individual who measures the outcome of interventions is not aware of the type of interventions.

Participants/Inclusion and exclusion criteria

Participants of patients with lateral epicondylitis referred to Beadat Hospital in Hamadan who have not responded to at least one course of non-steroidal anti-inflammatory drugs with no history of trauma, history of surgery , injection or physiotherapy at past 6 mounts. .

Intervention groups

Patients undergo rehabilitation in two different ways: biofeedback or ultrasound

Main outcome variables

severity of pain and problems during patients' daily activities and to punching power

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151123025202N6**

Registration date: **2020-01-10, 1398/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-10, 1398/10/20**

Update count: **0**

Registration date

2020-01-10, 1398/10/20

Registrant information

Name

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Name of organization / entity

Hamedan University of Medical Of Science

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between ultrasound therapy and biofeedback therapy in treatment of lateral epicondylitis

Public title

Treatment of lateral epicondylitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain in the external part of the elbow in at least 2 of the 4 tests of local pressure, wrist resistance extension, middle finger resistance extension, 2- to 5-finger resistance extension. Duration of symptoms for at least 6 weeks Failure to respond to at least one course with non-steroidal anti-inflammatory drugs

Exclusion criteria:

History of trauma in elbow Medical history of Surgery in elbow Injections or physiotherapy of elbow at past 6 months History of Steroid use over the past 3 months

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

For this purpose, we will use Sealed non-transparent envelopes. on 25 paper sheets of letter I meaning intervention and on 25 sheets of letter C means comparison. will be written. We mix the sheets together and place them in the envelopes and drawer of the table.. each time the patient is eligible, we randomly pull out one of the envelopes and open them according to the letter I or C written on the paper. They will be assigned to either intervention or comparison group, respectively. It should be noted that sampling will be non placement.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Science

Street address

Shahid Fahmideh Blv, Vice-Chancellor for Research and Technology of Hamedan, , Hamadan, Iran

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Approval date

2019-06-14, 1398/03/24

Ethics committee reference number

Ir.UMSHA.Rec.1398.234

Health conditions studied

1

Description of health condition studied

lateral epicondylitis

ICD-10 code

M77.1

ICD-10 code description

Lateral epicondylitis

Primary outcomes

1

Description

the power of painless hand punching

Timepoint

Before treatment, immediately after treatment and three months after treatment

Method of measurement

It will be measured using a dynamometer

2

Description

Restriction on hand, arm and shoulder use for daily, occupational, and social activities and hand, arm or shoulder pain score during working and activity

Timepoint

Before treatment, immediately after treatment and three months after treatment

Method of measurement

With Quick DASH questionnaire, VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:The biofeedback device is manufactured in Canada. The patients are treated with biofeedback for 5 sessions and 7 minutes each session. The procedure is that the electrodes are closed on the forearm extensor and flexor muscles according to the treatment protocol, and then a visual feedback is presented to the individual on the basis of computer equipment and the frequency range of the contraction

waves. The muscles strengthened in this process are primarily Extensor Carpi Radialis Brevis - Physiopedia and then Flexor carpi radialis, Flexor digitorum superficialis and Supinator and flexor wrist muscles will be inhibited. The main result of this study is effect strength and endurance of wrist and Wrist extensors extensors in lateral epicondylitis.

Category

Rehabilitation

2**Description**

control group: In the Ultrasound group, the SLE laser therapy, Ultrasound (1 and 3.3 MHz multiphase) and EIE Construction Electrotherapy in Poland will be used. This group will also be treated for 5 sessions and 7 minutes each session.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital

Full name of responsible person

Lobat Majidi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Hamedan 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**

Hamedan University of Medical Sciences

Full name of responsible person

dr Lobat Majidi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Position

MSc in epidemiology, MPH

Latest degree

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Other areas of specialty/work

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Position

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Latest degree

Master

Other areas of specialty/work

Epidemiology

Street address

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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

No more 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available