Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Name of organization / entity
Hamedan University of Medical Of Science

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Iran (Islamic Republic of)

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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
City
Hamadan
Province
Hamadan
Postal code
6517838677
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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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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Person responsible for scientific inquiries

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Position

MSc in epidemiology, MPH

Latest degree

Master

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Person responsible for updating data

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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