

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison effectiveness of microcurrent and exercise therapy on the pain and function in patients with Lateral Epicondylitis(Tennis Elbow disease)

Protocol summary

Study aim

Comparison effectiveness of microcurrent and exercise therapy on the pain and function in patients with Lateral Epicondylitis ,An unobserved clinical trial

Design

Sixty patients, are referred to the clinic with a physician specializing in hand approval with a diagnosis of Lateral Epicondylitis. The procedure will be explained to eligible patients, persons fills in the written consent.Each patient randomly selects an envelope containing the letter A or B, which represents the name of the intervention group.

Settings and conduct

Patients will initially be treated with a non-steroidal anti-inflammatory drug at the same dose and duration for initial pain relief. A group patients are exposed to 70 μ A electrical current for 15 minutes per session for 6 weeks and 3 sessions per week. In B group, patients will undergo exercise therapy intervention for 6 weeks and 3 sessions per week under the supervision of a physician. (Researcher blinding - one blind)

Participants/Inclusion and exclusion criteria

Inclusion criteria:All people aged 18 to 60 years who are referred from Specialized in hand surgery to Mostafavian Clinic Sports Medicine Center with a clinical diagnosis of Lateral Epicondylitis. Criteria for non-inclusion:have any contraindications to the use of microcurrent therapy and or Any history of shoulder or elbow fractures or history of dislocations in these areas during the past year, Any history of shoulder and elbow surgery in the last six months, Any phobia about treatment and suffering from chronic psychiatric disorders, Any allergies and contraindications to taking NSAIDs, Any history of cervical discopathy confirmed by imaging and sensory-motor symptoms (paresthesia) in the upper extremities

Intervention groups

A.Microcurrent therapy Group B. Exercise therapy group
This study has no control group.

Main outcome variables

Type of treatment, age, sex and occupation of the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140708018409N3**

Registration date: **2021-08-23, 1400/06/01**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-23, 1400/06/01**

Update count: **0**

Registration date

2021-08-23, 1400/06/01

Registrant information

Name

Gholamreza Partovi

Name of organization / entity

Mazandaran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 6552

Email address

ghpartovi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effectiveness of microcurrent and exercise therapy on the pain and function in patients with Lateral Epicondylitis(Tennis Elbow disease)

Public title
The effect of microcurrent device and exercise therapy in the treatment of patients with Tennis Elbow disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with Lateral Epicondylitis in the age range of 18 to 60 years who do not have criteria for not entering the interventions
Exclusion criteria:
Any contraindications to the use of microcurrent therapy, including: epilepsy, diabetes, immune system disorders, cancer, melanoma, metal implants (plates, pins, and screws) at the treatment site, open wounds, pacemaker, phlebitis, thrombosis , embolism, varicose veins and pregnancy Any history of shoulder or elbow fractures or history of dislocations in these areas during the past year Any history of shoulder and elbow surgery during the last six months Any phobias about treatment and suffer from chronic psychiatric disorders Any allergies and contraindications to the use of NSAIDs Any history of cervical discopathy confirmed by imaging and sensory-motor involvement symptoms (paresthesia) in the upper limb

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
There are two envelopes with names A and B, including microcurrent and exercise therapy group, inside the container and the patient chooses one. The selected envelope is then inserted into the container and the next patient selects one again

Blinding (investigator's opinion)
Single blinded

Blinding description
Considering that the patient knows in which group (exercise therapy or microcurrent therapy) but the

evaluator (supervisors) do not know which patient is in which group and all follow-ups are done by the sports medicine assistant and the evaluator only reviews the results It deals with questionnaires and recorded values of manual dynamometer, so this study is one-way blind.

Placebo
Not used

Assignment
Parallel

Other design features
Clinical trial without control group, with parallel groups, one-way blind, randomized

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research Mazandaran University of Medical Sciences, Moalem Square, Moalem Street

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2021-01-24, 1399/11/05

Ethics committee reference number

IR.MAZUMS.REC.1399.858

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

Patient-Rated Tennis Elbow Evaluation questionnaire (PRTEE)

Timepoint

Before the beginning and end of the intervention (sixth week) and 12 weeks after the end of the intervention

Method of measurement

Measurements are performed based on the values

obtained from PRTEE questionnaire

2

Description

Visual Analog Scale For Pain(VAS)

Timepoint

Before the beginning and end of the intervention (sixth week) and 12 weeks after the end of the intervention

Method of measurement

Measurements are performed based on the values obtained from VAS questionnaire

3

Description

Handheld dynamometer

Timepoint

Before the beginning and end of the intervention (sixth week) and 12 weeks after the end of the intervention

Method of measurement

Measurements are performed based on the values obtained from Handheld dynamometer .

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1:Exercise therapy:In this study, exercise therapy protocol was designed in a 6-week period of exercise to strengthen the elbow muscles focusing on the extensor muscles of the forearm involved in the pathology of lateral epicondylitis.Exercise sessions for 6 weeks 3 sessions per week according to the patient's tolerance based on the VAS scale are performed under the supervision of a sports medicine assistant at the clinic.Interventions including range of motion exercises, isometric, isotonic and eccentric exercises can be performed in three sets of 15 repetitions according to the patient's tolerance up to the experience of mild pain (4: VAS). Rest between sets will be 1-2 minutes.If the patient mentions debilitating pain (VAS: 8), the exercise is stopped and its intensity is recorded and it is performed with less intensity in the next sessions.When the patient reaches VAS: 0 in painless exercises, the intensity of the exercises is improved by using weights up to half a kilogram.Stretching exercises are performed in the form of static stretching performed by the patient him/herself with the support of the other hand. 6 stretches divided into 2 sets of 3 stretches are done at the beginning and end of exercise therapy with a time of 30 to 45 seconds of stretching and 30 seconds of rest between stretches.

Category

Treatment - Devices

2

Description

Intervention group 2: In this study,microcurrent interventionn by NU-TEK MT8000 COMBO STIMULATOR portable microcurrent device made in China for 6 weeks and 3 sessions of 15 minutes every week under 70 μ A current at the origin of the extensor muscles in the external epicondyle of the hand will be done.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mostafavian Clinic

Full name of responsible person

Dr Gholamreza Partovi

Street address

Razi 3

City

Sari

Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 6552

Email

ghpartovi@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

Street address

Vice chancellor for research Mazandaran University of Medical Sciences, Moalem Square, Moalem Street

City

Sari

Province

Mazandaran

Postal code

4471848178

Phone

+98 11 3325 7230

Email

pajooheshi@mazums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Gholamreza Partovi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Emam Khomeyni Hospital, Amir Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 6552
Fax
+98 11 3336 3754
Email
ghpartovi@mazums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Gholamreza Partovi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Emam Khomeyni Hospital, Amir Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code

4816633131
Phone
+98 11 3336 6552
Fax
+98 11 3336 3754
Email
ghpartovi@mazums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Gholamreza Partovi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Sport Medicine
Street address
Emam Khomeyni Hospital, Amir Mazandarani Ave
City
Sari
Province
Mazandaran
Postal code
4816633131
Phone
+98 11 3336 6552
Fax
+98 11 3336 3754
Email
ghpartovi@mazums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

results of statistical analysis and its analysis

When the data will become available and for how long

Start of access 12 months after printing results

To whom data/document is available

Health researchers

Under which criteria data/document could be used

view data

From where data/document is obtainable

corresponding author
What processes are involved for a request to access data/document

About 2 months
Comments