

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effectiveness of Integrated Neuromuscular Inhibition technique on pain, function, grip strength and muscles activity in patients with lateral epicondylitis.

Protocol summary

Study aim

Determining the effectiveness of Integrated Neuromuscular Inhibition Technique on pain, function, grip strength, and muscle activity in patients with lateral epicondylitis.

Design

Clinical trial includes two groups of intervention and control, one blinded, Randomization in the form of permutation blocks.

Settings and conduct

This trial will be conducted at Zahedan University of Medical Sciences. Patients are blinded to the treatment. Patients are explained about the study. After obtaining informed consent, randomization will be performed. The initial size of the variables will be recorded. Individuals in each group will receive the treatment three times a week, for 4 continuous weeks, and at the end, the variables are recorded again.

Participants/Inclusion and exclusion criteria

Inclusion : Age between 18 to 60 years. Pain intensity at the initial visit should be at least 3. Unilateral elbow pain lasting more than 3 months. Tenderness near or on the lateral epicondyle. Positive 3 of the following 4 test: Grip strength, Cozen, Mill, Maudsley. No cardiovascular disease. No neurological disease. No neuromuscular disease or nerve entrapment. No history of trauma to the lateral epicondyle. No history of previous surgery. No other treatment in the last 6 months. Exclusion : No willingness to receive manual therapy. Failure to complete treatment sessions. Exacerbation of symptoms or patient dissatisfaction with the continuation of sessions.

Intervention groups

1- Intervention group: In addition to routine treatment, also receives Integrated Neuromuscular Inhibition Technique(INIT); it includes several manual treatments (ischemic pressure, strain-counterstrain, and muscle

energy technique). 2- Control group: only received routine physiotherapy treatments; included: hot pack, TENS, ultrasound, education and exercises.

Main outcome variables

Pain; Disability; Grip strength; Muscle activity.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220626055278N3**

Registration date: **2025-05-05, 1404/02/15**

Registration timing: **prospective**

Last update: **2025-05-05, 1404/02/15**

Update count: **0**

Registration date

2025-05-05, 1404/02/15

Registrant information

Name

Hassan Namvar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effectiveness of Integrated Neuromuscular Inhibition technique on pain, function, grip strength and muscles activity in patients with lateral epicondylitis.

Public title

Investigating the effectiveness of Integrated Neuromuscular Inhibition technique in patients with lateral elbow pain.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 60 years. The patient's pain intensity at the initial visit should be at least 3 on the Visual Analog scale. Unilateral elbow pain that lasts more than 3 months. Tenderness near or over the lateral epicondyle. Positive results in 3 of the following 4 tests to confirm epicondylitis: grip strength test, Cozen test, Mill test, Maudsley test. Absence of cardiovascular disease. Absence of neurological diseases. Absence of neuromuscular diseases and nerve entrapments. No history of trauma to the lateral epicondyle. No history of previous surgery. No other treatment received in the last 6 months.

Exclusion criteria:

Failure to complete treatment sessions. Exacerbation of symptoms or patient dissatisfaction with the continuation of treatment sessions.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be easy and accessible, taking into account the characteristics of the entry. A permutation block randomization method will be used to assign individuals to groups. Initially, individuals will be randomly divided into four equal blocks by drawing lots and numbered. Then, the block numbers are randomly selected by a person who is not involved in the sampling process so that the blocks are placed in two different treatment groups, respectively, until the groups reach the desired sample size.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be unaware of the grouping. Physiotherapy modalities are explained to the patients and they are told that modalities and manual therapy are used in their treatment, but they will be unaware of what approach are used in each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences.

Street address

Dr. Hesabi Square, Imam Hossein Blvd, compus of university of medical sciences.

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Postal code

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Approval date

2025-04-13, 1404/01/24

Ethics committee reference number

IR.ZAUMS.REC.1404.025

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**

Pain that is more than 3 or 3 befor intervention.

Timepoint

Measurement befor the start of the intervention and 4 weeks after the application of the intervention.

Method of measurement

Visual Analoge Scale.

2

Description

Function.

Timepoint

Measurement before the start of the intervention and 4 weeks after the application of the intervention.

Method of measurement

Patient Rated Tennis Elbow Evaluation Questionnaire.

3

Description

Grip strength.

Timepoint

Measurement before the start of the intervention and 4 weeks after the application of the intervention.

Method of measurement

Dynamometer device.

4

Description

Muscle activity.

Timepoint

Measurement before the start of the intervention and 4 weeks after the application of the intervention.

Method of measurement

Surface Electromyography Device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: includes Integrated Neuromuscular Inhibition Techniques with routine physiotherapy. This technique includes several different manual therapies: Ischemic pressure, Strain Counter Strain, and Muscle energy techniques. After finding tender point at the lateral epicondyle, pressure is applied for 90 seconds, then the patient is given a rest, and this procedure is repeated 3 times. To perform the strain-contrastrain technique, we move the patient's wrist to a position that reduces the patient's pain by at least 70 percent, maintain pressure in this position for 90 seconds, and repeat this process 3 times. To perform the Muscle Energy Technique, we bend the patient's wrist slightly and obtain a resistive contraction in the direction of wrist extension from the patient. Hold the contraction for 7 seconds and then rest. During the rest period, the wrist is further flexed and this process is repeated 3 times. Finally, a soft tissue extensor stretch is performed for 30 seconds.

Category

Rehabilitation

2

Description

Control group: This group only received routine physiotherapy treatments, including: hot packs, transcutaneous electrical nerve stimulation, ultrasound, education and exercises. The hot pack is placed on the epicondyle for 20 minutes. Transcutaneous electrical nerve stimulation with frequency of 60 Hertz and pulse duration of 100 milliseconds and tolerable intensity of 10 to 30 milliamps for 20 minutes, will be applied through two electrodes that we are placing on the extensor origin muscle of the patient. Ultrasound waves with frequency of 1 MHz and an intensity of 1.5 watts/cm² are applied around the lateral epicondyle for 3-5 minutes. Transcutaneous electrical nerve stimulation and ultrasonic waves will be performed by devices manufactured by Novin Medical Engineering company. Patient education includes avoiding lifting, repetitive wrist activities, using screwdrivers and mice, and any activity that aggravates pain. The patient's exercises include 3 groups: 1- Stretching of the wrist extensors and flexors, each stretch should be maintained for 30 seconds and repeated 3 times. 2- Active flexion and extension movements of the patient's wrist and elbow, each movement includes 3 sets and each set has 20 repetitions. 3- Isometric grip and wrist extension movements, each contraction should be maintained for 20 seconds and has 20 repetitions.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Razmjoomoghadam Physiotherapy Clinic

Full name of responsible person

Maryam Sargolzehi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Arezu Naseri

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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