Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 aproach 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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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 befor 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 befor 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 befor 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 CounterStrain, 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 origion 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
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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

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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