Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Determining the effect of dry needling combination with counterforce brace on pain, grip strength, and upper limb function in individuals with lateral epicondylitis

Protocol summary

Study aim
Determining the average pain and grip strength and upper limb function, severity of disability and quality of life in people with lateral epicondylitis in three groups

Design
The present study is a single-blind randomized clinical trial in which 39 patients who meet the inclusion criteria were included in the study as available cases and will be randomly assigned to one of three intervention groups: Group 1 (routine physiotherapy treatment), Group 2 (dry needling treatment + routine physiotherapy) and Group 3 (dry needling treatment + counterforce brace + routine physiotherapy).

Settings and conduct
Patients with symptoms of lateral epicondylitis presented to the physiotherapy clinic in Tehran city after completing an informed consent form to participate in the study and the patients will be randomly divided into three groups. Participants in each group will be assessed before the intervention begins, after it ends, and 1 month after the intervention ends.This study is designed as a single-blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People whose dominant hand is involved; No contraindications for using dry needles; Pain on palpation of the external epicondyle of the humerus in the dominant hand; Cozen's test is positive; Middle finger resistance test is positive; They have not responded to conservative treatment in the past 6 months; No history of corticosteroid injections in the past 6 months
Exclusion criteria: peripheral nerve involvement; History of trauma and fracture in the upper limb; Taking NSAID drugs; Patients who do not want to continue treatment for any reason.

Intervention groups
Group one: routine physiotherapy Group two: routine physiotherapy with dry needling Group three: routine physiotherapy with dry needling and counterforce brace

Main outcome variables
Pain, grip strength, and upper limb function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250224064842N1**
Registration date: **2025-04-30, 1404/02/10**
Registration timing: **prospective**

Last update: **2025-04-30, 1404/02/10**
Update count: **0**

Registration date
2025-04-30, 1404/02/10

Registrant information

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razieh jafari

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
2025-06-05, 1404/03/15

Expected recruitment end date
2025-09-22, 1404/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determining the effect of dry needling combination with counterforce brace on pain, grip strength, and upper limb function in individuals with lateral epicondylitis

Public title
Determining the effect of dry needling combination with counterforce brace on lateral epicondylitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People whose dominant hand is involved No contraindications for using dry needles Pain on palpation of the external epicondyle of the humerus in the dominant hand Cozen's test is positive They have not responded to conservative treatment in the past 6 months No history of corticosteroid injections in the past 6 months
Exclusion criteria:
Age
From **18 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **39**
Randomization (investigator's opinion)
Randomized
Randomization description
Three envelopes with the names of the groups written inside and sealed, and we ask the patient to choose one envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person who measures and evaluates variables in patients does not know the type of patient intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of medical Sciences
Street address
Shahid Beheshti University of Medical Sciences, Arabi St, Daneshjoo Blvd ,Valenjak, Tehran
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Approval date
2025-02-09, 1403/11/21
Ethics committee reference number
IR.SBMU.RETECH.REC.1403.760

Health conditions studied

1

Description of health condition studied
Lateral epicondylitis (Tennis elbow)
ICD-10 code
M77.1
ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
Pain
Timepoint
Before the intervention and after the intervention and one month later
Method of measurement
Visual Analogue Scale

2

Description
Grip strength
Timepoint
Before the intervention and after the intervention and one month later
Method of measurement
Dynamometer

3

Description
Upper limb function
Timepoint
Before the intervention and after the intervention and one month later
Method of measurement
Quick Dash questionnaire

4

Description
Pressure pain threshold
Timepoint
Before the intervention and after the intervention and one month later
Method of measurement
Algometer

5

Description
Quality of life
Timepoint
Before the intervention and after the intervention and one month later
Method of measurement
36-question quality of life questionnaire (SF-36)

Secondary outcomes

1

Description
Severity of disability
Timepoint
Before the intervention and after the intervention and one month later
Method of measurement
Patient-Rated Tennis Elbow Evaluation Questionnaire

Intervention groups

1

Description
First intervention group: Control group: treatment in group 1 (routine physiotherapy) is performed in a way that includes stretching exercises of the wrist extensor muscles for 30 seconds with 5 repetitions and ultrasound with an intensity of 1.5 for 3 minutes in the painful area and deep friction massage for 5 minutes.
Category
Rehabilitation

2

Description
Second intervention group: Treatment in group 2 (routine physiotherapy and dry needling) immediately after the routine physiotherapy, the patient is placed in an open arch position, the elbow is slightly bent, the forearm is in a normal position and a pillow is placed under the hand. After cleaning the skin, 5 dry needles 0.25 x 25 mm (needle size varies depending on the size of the muscle) will be inserted in the external epicondyle area and in the trigger points of the extensor carpi radialis brevis tendon .We find the extensor carpi radialis brevis tendon by resisting raising the third finger. Then rotate the needle 3 to 4 times and it will remain in place for 10 minutes and will be pulled out. To perform dry needling twice in the first and second weeks (three days between each session) and once in the third week, dry needling is repeated and routine physiotherapy will be performed immediately after applying dry needling.
Category
Rehabilitation

3

Description
Third intervention group: In group 3 (dry needling, routine physiotherapy, and brace), it is done in such a way that the brace is used immediately after dry needling and routine physiotherapy. The prefabricated Counterforce brace is closed 5 cm below the origin of the wrist extensor tendon according to the size of the patient. To make sure, under the supervision of an orthotist, patients bend and straighten their elbow so that the brace does not interfere with their range of motion and does not slip.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shafabakhsh physiotherapy
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shahid Beheshti 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
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Physiotherapy Master's student
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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