

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

Name

raziieh jafari

Name of organization / entity

Country

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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Postal code

1985717443

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

Razieh jafari

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No253, 1th Floor, Unit4, Nahidi Alley, Tehranpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Web page address

https://isid.research.ac.ir/Afshin_Zarghi

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Razieh jafari

Position

Physiotherapy Master's student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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