Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of short-term and long-term effects of dry needling, shock wave therapy and corticosteroid injection on pain and sonographic findings of patients with tennis elbow: Randomized controlled clinical trial

Protocol summary

Study aim
Evaluation of short-term and long-term effects of dry needling, shock wave therapy and corticosteroid injection on pain and sonographic findings of patients with tennis elbow

Design
A randomized, controlled, blinded, clinical trial with a parallel group design of 68 patients

Settings and conduct
The present study would be designed to evaluate the effects of dry needling, shockwave therapy and corticosteroid injection in patients with tennis elbow. All procedures will be performed in poursina hispital, Guilan university of medical sciences. The patients will be in 4 groups single blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 30 and 55 years; Tennis elbow disease diagnosed by an orthopedic specialist. Pain in the lateral epicondyle region that increases with palpation. - Exclusion criteria: 1- People with other painful disease or disorders in shoulder and neck. 2- People who have continuously done physiotherapy or exercise during the last two weeks.

Intervention groups
Group A: Drug therapy and elbow splint: Naproxen 500 and elbow splint for 4 weeks. Group B: Drug therapy and elbow splint + corticosteroid injection: Group A treatments plus one ml of corticosteroid (Betamethasone) and lidocaine into the common extensor tendon. Group C: Drug therapy and elbow splint + dry needling: Group A treatments plus three needles in the area of the trigger points and painful tendon. Group D: Drug therapy and elbow splint + shockwave therapy: Group A treatments plus shockwave therapy on the most sensitive point of the tendon and its surroundings at a rate of 2000 pulses.

Main outcome variables
Pain, echogenicity intensity and common extensor tendon thickness.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20170516034003N10**
Registration date: **2025-02-26, 1403/12/08**
Registration timing: **retrospective**

Last update: **2025-02-26, 1403/12/08**
Update count: **0**

Registration date
2025-02-26, 1403/12/08

Registrant information

Name
Kamran Ezzati

Name of organization / entity
Guilan University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 13 3369 0099

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-20, 1402/10/30

Expected recruitment end date

2024-06-19, 1403/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of short-term and long-term effects of dry needling, shock wave therapy and corticosteroid injection on pain and sonographic findings of patients with tennis elbow: Randomized controlled clinical trial

Public title

The effects of dry needling, shock wave therapy and corticosteroid injection in patients with tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Visual analogue scale (VAS) score of 3 or more Pain in the lateral epicondyle region of the elbow, which increases when palpating the external tendons.

Exclusion criteria:

People with neuropathy such as thyroid problems. People with neck and shoulder myopathy. People with a history of neck and shoulder, elbow and wrist surgery. People with cancer, infection, pain and lung disease, acquired immunodeficiency virus. People with psychosocial disorders who were evaluated using the Persian version of the DASS-21 stress-anxiety-depression questionnaire and obtained scores above the normal range. (Normal scores: maximum 9= depression, maximum 7 = anxiety, maximum 14 = stress) Patients with osteochondritis of lateral epicondyle, osteoarthritis of the lateral compartment of the elbow, varus instability and the presence of radial tunnel syndrome.

Age

From **30 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, all participants will have an equal chance of being assigned to each of the study groups. In this study, 64 patients with tennis elbow will be divided into four groups through block randomization with a block size of 8 in 8 blocks. Sequence generation was obtained through the sealed envelope site (www.sealedenvelope.com/simple-randomiser/v1/lists) as follows. Allocation concealment will be done through sealed envelopes. In this way, the obtained sequence is placed in envelopes in order. Then, for each patient who visits, the envelope that is in the selection queue is removed and if the letter A is observed, the first group intervention will be performed for the patient. If the letter B is observed, the second group intervention will be performed and similarly with the letters C and D, the third and fourth group interventions will be performed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The examiner and statistical analyzer won't know anything about the kind of treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

5th floor, Central office of Guilan University of Medical Sciences, Namjoo St., Rasht, Iran

City

Rasht

Province

Guilan

Postal code

۴۱۹۳۷۱۳۱۹۴

Approval date

2023-06-14, 1402/03/24

Ethics committee reference number

IR.GUMS.REC.1402.154

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

Timepoint
Before intervention, After treatments, 3 month follow-up
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
echogenicity intensity
Timepoint
Before intervention, After treatments, 3 month follow-up
Method of measurement
Using ultrasonography

2

Description
Common extensor tendon thickness
Timepoint
Before intervention, After treatments, 3 month follow-up
Method of measurement
Using ultrasonography

Intervention groups

1

Description
Control group: Drug therapy and the use of splints or elbow braces are considered as the usual treatment for tennis elbow. Drug treatment for all patients will be done in the form of naproxen 500 tablets, one daily for up to three weeks. The splint will allow movement of the wrist, fingers and elbow and will place the wrist in 5 degrees of extension. This splint will be used for 6 to 8 hours a day and for 4 weeks. It should be noted that due to ethical considerations, treatment will be performed in all studied groups.
Category
Treatment - Drugs

2

Description
Intervention group: Injection treatment: In this method, one milliliter of corticosteroid (Betamethasone) is injected into the common extensor tendon along with lidocaine.
Category
Treatment - Drugs

3

Description
Intervention group: dry needling: In this method, after cleaning the skin, three needles (0.25 x 50 mm) and (Tony, Stockholm, Sweden) will be inserted back and forth in the trigger points and painful tendon area. These needles are rotated 5 times and will remain in place for 10 minutes. This whole process will be repeated twice with a ten minute rest interval. After the needle is removed, the desired area is pressed with cotton to prevent bleeding. This procedure will continue for three times a week and up to ten sessions. Dry needling was performed by a skilled physiotherapist with more than ten years of experience
Category
Rehabilitation

4

Description
Intervention group: shockwave therapy:shockwave therapy will be performed using a shockwave device (BTL, SWT TOPLINE UK). The parameters used will be: 10 Hz, 2000 pulses, 2-4 bar pressure. The patient will be placed in a supine position, the elbow slightly bent and the forearm pronated. The R15 shock wave therapy applicator will be placed on the most sensitive point and around it. No topical ointment will be used before the treatment. The treatment will be done two days a week for ten sessions
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina hospital
Full name of responsible person
Kamran Ezzati
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Elahe Rafie
Position
Bachelor of science
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Sharing is done after the end of the study. The total potential data can be shared after unidentifications of individuals.

When the data will become available and for how long

Start the access period 6 months after publicating the results

To whom data/document is available

Researchers working in universities

Under which criteria data/document could be used

- Research that is in line with current study. - Data correlation analysis is allowed. -It is preferred to have a university degree and be a researcher in the desired field.

From where data/document is obtainable

Adress: Physiotherapy section, Block 2, , Poursina hospital, Namjoo St, Rasht. Kamran Ezzati Ez_kamran@yahoo.com

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

A written request for data from the relevant university with the name and academic degree of the researcher

Comments