Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of acupuncture versus mesotherapy in the treatment of tennis elbow compared to the control group (oral medication and splinting alone)

Protocol summary

Study aim
Investigating the effect of acupuncture versus mesotherapy in the treatment of tennis elbow compared to the control group

Design
The clinical trial has a control group, with parallel groups, randomized, phase 2 on 54 patients, the random allocation method in this study will be the permutation block method of 6.

Settings and conduct
Patients referred to the physical medicine and rehabilitation clinics of Shiraz University of Medical Sciences are divided into three groups. The first group is administered oral naproxen 500 mg tablets twice a day (once every twelve hours) for 7 days. The second group Mesotherapy with piroxicam is used in the desired acupuncture points and the maximum tenderness point with a combination of 1 cc of 20 mg piroxicam and 4 cc of 2% lidocaine on two occasions of 0 and 7 days.The third group of acupuncture is inserted in the desired acupuncture points and points with maximum tenderness. Acupuncture sessions are performed for 4 weeks and between 2 to 3 times per week. Patients benefit from joint treatment of stretching exercises and strengthening wrist extensors.

Participants/Inclusion and exclusion criteria
Patients who have been at least 3 months since the onset of symptoms and have not responded to initial and conservative treatments are included in the study, and patients with any elbow injection, elbow and upper limb physiotherapy during the past 3 months are excluded from the study.

Intervention groups
Group A: oral naproxen and stretching and strengthening exercises for wrist extensor muscles + cock up splint Group B: Piroxacam and lidocaine mesotherapy + stretching exercises and strengthening the wrist extensor muscles Group C: Acupuncture and stretching exercises and strengthening the wrist extensor muscles

Main outcome variables
Amount and severity of pain and functional limitations of patients with tennis elbow

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250122064481N1**
Registration date: **2025-01-24, 1403/11/05**
Registration timing: **prospective**

Last update: **2025-01-24, 1403/11/05**
Update count: **0**

Registration date
2025-01-24, 1403/11/05

Registrant information

Name
Mahshid Malekmohamadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-19, 1403/12/01

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
Investigating the effect of acupuncture versus mesotherapy in the treatment of tennis elbow compared to the control group (oral medication and splinting alone)

Public title
Investigating the effect of acupuncture versus mesotherapy in the treatment of tennis elbow compared to the control group (oral medication and splinting alone)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Completing and signing the consent form Clinical diagnosis of tennis elbow in the form of pain in the external epicondyle region of the humerus bone by local pressure and wrist extension against resistance Age between 25 and 70 years At least 3 months have passed since the onset of symptoms They have not responded to primary and conservative treatments
Exclusion criteria:
Any clinical symptoms of effusion, inflammation, redness and warmth of the involved area Having uncontrolled diabetes, rheumatic diseases and vascular collagen, myopathy, any serious systemic and local infection, Brucella, bleeding diseases History of surgery in the elbow joint of the affected side Severe deformity of the upper limbs Inability to communicate and complete questionnaires History of allergies and allergic reactions to the drugs used, history of significant liver, kidney, brain and cardiopulmonary disorders, history of injections in or around the affected joint in the last 3 months, history of elbow and upper limb physiotherapy in the last 1 month Stable use of NASID in the last 48 hours Pregnant and lactating women, people with cancer People who are using anticoagulants
Age
From **25 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **54**
More than 1 sample in each individual
Number of samples in each individual: **18**
The study of a clinical trial on 54 patients in three treatment groups, each treatment group includes 18 patients, and the therapeutic interventions of the groups are compared.
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization: The random allocation method in this study will be the permutation block method of 6 such that A represents the person who receives intervention 1, B represents the person who receives intervention 2, and C represents the person who is placed in the control group. How to hide the allocation of participants: 1.
A_____ 2.
C_____ 3.
C_____ 4.
C_____ 5.
A_____ 6.
B_____ 7.
B_____ 8.
B_____ 9.
C_____ 10.
A_____ 11.
B_____ 12.
C_____ 13.
C_____ 14.
B_____ 15.
A_____ 16.
A_____ 17.
A_____ 18.
B_____ 19.
B_____ 20.
B_____ 21.
C_____ 22.
A_____ 23.
B_____ 24.
A_____ 25.
B_____ 26.
C_____ 27.
A_____ 28.
C_____ 29.
A_____ 30.
A_____ 31.
B_____ 32.
C_____ 33.
A_____ 36.
C_____ 35.
C_____ 36.
B_____ 37.
B_____ 38.
B_____ 39.
C_____ 40.
A_____ 41.
C_____ 42.
B_____ 43.
B_____ 44.
A_____ 45.
C_____ 46.
A_____ 47.
A_____ 48.
C_____ 49.
B_____ 50.
A_____ 51.
A_____ 52.
C_____ 53.
B_____ 54.
C_____ In order to hide the random sequence method, another person who is unaware of the research process is provided, and the

questionnaires are completed by a person who is unaware of the division of the groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The differences of opinion among the treatment methods for tennis elbow and the lack of a study comparing the effect of mesotherapy and acupuncture against the control group in the treatment of these patients, due to the safety and low cost of these two treatment methods and the absence of side effects Other treatment methods such as side effects caused by corticosteroid injection, this study was conducted with the aim of comparing these treatment methods.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
No.6 Eram dormitory, Eram square

City
Shiraz

Province
Fars

Postal code
7194685791

Approval date
2025-01-20, 1403/11/01

Ethics committee reference number
IR.SUMS.MED.REC.1403.680

Health conditions studied

1

Description of health condition studied
Tennis elbow

ICD-10 code
M77.1

ICD-10 code description
Lateral epicondylitis

Primary outcomes

1

Description
intensity of pain

Timepoint
Before starting the treatment and 2 and 4 weeks after the treatment

Method of measurement
Visual Analog Scale

2

Description
performance

Timepoint
Before starting the treatment and 2 and 4 weeks after the treatment

Method of measurement
Patient-Rated Tennis Elbow Evaluation

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group: to perform mesotherapy with piroxicam, we insert the needle into the skin at an angle of 10 degrees and horizontally. The needle entry point is the acupuncture points Lu5, Li10, Li11, Li12 and the maximum tenderness point, which is composed of one cc of piroxicam 20 mg. And 4 cc of 2% lidocaine is used in each point with a depth of one to three millimeters and on two occasions of 0 and 7 days. Injections are performed using 5 cc disposable sterile syringes with a thin needle head (0.27 mm x 4 mm).Stretching exercises (for two weeks) and strengthening of wrist extensors (after two weeks) are used. The duration of each exercise is 15 to 30 seconds and is repeated 10 to 30 times a day according to the patient's tolerance.

Category
Treatment - Drugs

2

Description
The second intervention group: A special acupuncture needle with a size of 13 x 18 cm is used to perform acupuncture. The needle entry point is the acupuncture points Lu5, Li10, Li11, Li12 and points with maximum tenderness. The depth of needle insertion is selected according to the recommendations of traditional Chinese acupuncture for classic points and the needles are removed after 25 minutes. Acupuncture sessions are performed for 4 weeks and between 2 to 3 sessions per week (on average, each patient has at least 10 sessions during He is treated with acupuncture for 4 weeks.Stretching exercises (for two weeks) and strengthening of wrist extensors (after two weeks) are used. The duration of each exercise is 15 to 30 seconds and is repeated 10 to 30 times a day according to the patient's tolerance.

Category

Treatment - Devices

3

Description
Control group: Oral naproxen tablets of 500 mg are used twice a day (once every twelve hours) for a period of 7 days.Stretching exercises (for two weeks) and strengthening of wrist extensors (after two weeks) are used. The duration of each exercise is 15 to 30 seconds and is repeated 10 to 30 times a day according to the patient's tolerance.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rajaei hospital

Full name of responsible person
Hossein Alikhalili

Street address
Shahid Chamran Blvd

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2

Recruitment center

Name of recruitment center
Imam Reza (a.s.) special specialized and super-specialized clinic

Full name of responsible person
Ali jangjou

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamid Mohamadi

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Web page address
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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mahshid Malekmohamadi

Position
Physical medicine and rehabilitation Resident

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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Person responsible for updating data

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Other areas of specialty/work
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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
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
Title and more details about the data/document
The results of completing the questionnaires on improving pain and function are published without mentioning the names and personal information of the patients.
When the data will become available and for how long
The access period starts after the results are printed
To whom data/document is available
Only for researchers working in academic and scientific institutions
Under which criteria data/document could be used
Only data analysis in terms of quality of life improvement in tennis elbow patients is allowed.
From where data/document is obtainable
malekmohammadi@sums.ac.ir
What processes are involved for a request to access data/document
3 to 6 months after receiving the applicant's email
Comments