

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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: Piroxicam 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)

Phone

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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

AgeFrom **25 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked

No information

Sample sizeTarget 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

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 centers1**Recruitment center****Name of recruitment center**

Rajaei hospital

Full name of responsible person

Hossein Alikhalili

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<https://rajaeehosp.sums.ac.ir>

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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Namazi Square, next to Namazi Hospital

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

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

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 scientific inquiries

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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

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