Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

Investigation of the effect of mesotherapy with piroxicam in the treatment of tennis elbow in comparison with oral medical therapy in terms of improving pain and function

Protocol summary

Study aim
Comparing the effectiveness of piroxicam mesotherapy with oral medical treatment in improving pain and function in patients with tennis elbow

Design
The research is a randomized double blind clinical trial on 36 patients.

Settings and conduct
Samples are selected from patients with tennis elbow referred to Imam Reza Clinic, Rajaee and Faghihi Hospitals divided into two groups. Block Randomization Assignment and Double blind methods are used. After obtaining informed consent, oral medical treatment is done with naproxen in control group and piroxicam mesotherapy is performed in intervention group. Finally, effects on improving pain and function are measured.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 20-60 years, clinical diagnosis of tennis elbow by local pressure and wrist extension against resistance, pain lasting more than 1 month with a VAS score of at least 4. Exclusion criteria: Any effusion, inflammation, redness and warmth in affected elbow, uncontrolled diabetes, rheumatic and vascular collagen diseases, cervical radiculopathy, neuropathy, myopathy in upper limb, serious systemic and local infection, history of surgery, trauma, fracture, dislocation in affected elbow joint, severe deformity in upper limb, bleeding disorders, taking anticoagulants, inability to communicate and complete questionnaires, allergies to medications used, significant liver, kidney, gastrointestinal, cerebral and cardiopulmonary disorders, history of injections in or around affected joint in past three months, history of elbow and upper limb physiotherapy in past one month, pregnant, lactating women, cancer, malignancy, use of NSAIDs in last 48 hours and corticosteroids in last two weeks.

Intervention groups
Intervention group undergoes piroxicam mesotherapy in affected elbow. Control group undergoes oral medical treatment.

Main outcome variables
Pain, Activity of daily living

General information

Reason for update

Acronym
LET

IRCT registration information
IRCT registration number: **IRCT20230515058198N1**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **0**

Registration date
2023-07-24, 1402/05/02

Registrant information

Name
Zahra Zare

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3231 5768

Email address
niloofarzare@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-01, 1402/05/10

Expected recruitment end date

2024-03-30, 1403/01/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of mesotherapy with piroxicam in the treatment of tennis elbow in comparison with oral medical therapy in terms of improving pain and function

Public title

Investigating the effect of piroxicam mesotherapy in the treatment of tennis elbow

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 applying local pressure and wrist extension against resistance At least one month has passed since the onset of the patient's symptoms Having a pain Visual Analogue Scale of at least 4

Exclusion criteria:

Any signs and symptoms of effusion, inflammation, redness and warmth of the affected area Having uncontrolled diabetes mellitus Having rheumatic and collagen vascular disorders Suffering from active cervical radiculopathy, neuropathy or myopathy simultaneously in the upper limbs Having any type of serious systemic and local infection History of surgery, trauma, fracture and dislocation in the elbow joint on the affected side, severe deformity in the upper limb Individuals with bleeding disorders and/or taking anticoagulants History of allergies and allergic reactions to the medications used History of significant liver, kidney, gastrointestinal, cerebral and cardiopulmonary disorders, history of gastrointestinal bleeding History of injections in or around the affected elbow joint in the last three months History of elbow and upper limb physiotherapy in the last one month Taking non-steroidal anti-inflammatory drugs (NSAIDs) in the last 48 hours and steroidal anti-inflammatory drugs in the last two weeks Pregnant women and lactating women Individuals with cancer Inability to communicate and complete questionnaires

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into two groups by Block Randomization Assignment and double blind methods. We will have two lists of 18 patients including the intervention and control groups, at random. For concealment, method of random sequencing is given to another individual who is unaware of the research process. All questionnaires will be completed by an individual unaware of the division of groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant: in this study, we do not have the ability to blind the participant because the participants are aware of receiving each intervention. Clinical care giver: we instruct the caregiver how to complete the questionnaires. This person is not aware of receiving patient’s intervention. Researcher: this study does not have the ability to blind the researcher due to performing both interventions by himself and being aware of receiving the kind of intervention in each group. The outcome assessor of the completed questionnaires is given to an individual who is not aware of the interventions and he/she is asked to determine the level of performance in each subject according to the questionnaires. Data analyzer: questionnaire are finally given to a person to review the information. This person does not know any of the steps of the study and the way of classification in which the interventions performed.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

7th floor, unit 52, Imam Hossein dormitory medical science building, 36th alley, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

7135744661

Approval date

2023-05-06, 1402/02/16

Ethics committee reference number

IR.SUMS.MED.REC.1402.081

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
Upper limb pain
Timepoint
Before intervention, two weeks and four weeks later
Method of measurement
Visual Analogue Scale (VAS); Patient-Rated Tennis Elbow Evaluation (PRTEE)

Secondary outcomes

1

Description
Function of patient
Timepoint
Before intervention, two weeks and four weeks later
Method of measurement
Patient-Rated Tennis Elbow Evaluation (PRTEE)

Intervention groups

1

Description
Intervention group: Subcutaneous injection (mesotherapy) of 1 ml piroxicam 20 mg/ml with 1 ml lidocaine 2% is applied in the acupuncture points Lu6, Li10, Li11, Li12 and the maximal tender point of the affected elbow. Mesotherapy is performed in 2 sessions at intervals of one week according to the common and sterile protocol along with lifestyle modification, doing stretching and strengthening exercises of the wrist extensor muscles and using tennis elbow band. The patients have to complete the Visual Analog Scale and Patient-Rated Tennis Elbow Evaluation questionnaires before entering the study and 2 and 4 weeks after intervention.
Category
Rehabilitation

2

Description
Control group: Oral naproxen 500 mg twice a day (one every 12 hours) is used for seven days. Oral medical treatment is done along with lifestyle modification, doing stretching and strengthening exercises of the wrist extensor muscles and using tennis elbow band. The patients have to complete the Visual Analog Scale and Patient-Rated Tennis Elbow Evaluation questionnaires before entering the study and 2 and 4 weeks after intervention.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza rehabilitation clinic
Full name of responsible person
Mani Ramzi
Street address
Namazi square
City
Shiraz
Province
Fars
Postal code
714737-71348
Phone
+98 71 3212 7700
Email
motahari@sums.ac.ir

2

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
Amir Reza Mesbahi
Street address
Chamran Blvd
City
Shiraz
Province
Fars
Postal code
7194815711
Phone
+98 71 3636 4001
Email
Rajaeehospital@sums.ac.ir

3

Recruitment center
Name of recruitment center
Shahid Faghihi Hospital
Full name of responsible person
Amir Reza Dehghanian
Street address
Zand St
City
Shiraz

Province
Fars
Postal code
7134846114
Phone
+98 71 3235 1087
Email
FaghihiHsp@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Front of Maaref school; Khalili Avenue
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3628 1506
Email
Info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
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
Zahra Zare
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
7th floor, unit 52, Imam Hossein dormitory medical science building, 36th alley, Zand Blvd.
City
Shiraz
Province
Fars
Postal code
7135744661
Phone
+98 71 3231 5768
Email
niloofarzare@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Zare
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Resident
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Phone
+98 71 3231 5768
Email
niloofarzare@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Zahra Zare
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
Street address
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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
All available data can be shared after making people unidentifiable.
When the data will become available and for how long
Start access period one year after publishing the results
To whom data/document is available
Everyone can access to this information.
Under which criteria data/document could be used
If the information in this study helps to improve the science process.
From where data/document is obtainable
Dr. Zahra Zare, 00989173296042, niloofarzare@sums.ac.ir
What processes are involved for a request to access data/document
After sending the desired message, all authors of the study will be consulted. All information will be sent within a maximum of three weeks if permitted.
Comments