Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the Efficacy of ultrasound guided injection of Corticosteroid, Platelet-rich Plasma(PRP), and Ozone on pain and function of patients with lateral epicondylitis: A multicenter randomized clinical trial

Protocol summary

Study aim
comparing the efficacy of us-guided injection of corticosteroid, PRP, and ozone on pain and function of patients with lateral epicondylitis

Design
A controlled, parallel-group, double-blind, randomized,clinical trial on 90 patients

Settings and conduct
Blindness: patients, interventionist, outcome assessor, statistician and the researcher US guided injection of 90 patients with tennis elbow randomly assigned into 3 groups of 30(steroid,PRP and ozone) Follow up 2 and 6 months after injection Place of study: Modares hospital and Modava pain clinic

Participants/Inclusion and exclusion criteria
Inclusion criteria: treatment-resistant tennis elbow duration of 3 months or more pain intensity of VAS 5 or more age of 20 to 50 years / Exclusion criteria: Symptoms of an infectious disease or fever in the last few days Thyroid dysfunction or uncontrolled diabetes Rheumatic disease History of blood or bone malignancy Elbow joint injury Carpal tunnel syndrome and other peripheral nerve injuries Cervical radiculopathy Hx of autoimmune disease Platelet dysfunction Treatment with antiplatelet drugs in the last 10 days Platelets<150,000 Treatment with NSAID within 48 hours before injection Steroid use in the past 3 weeks Hb<10 Pregnancy or breastfeeding Treatment of tennis elbow with steroids in the last 6 months Lateral epicondylitis surgery Ozone sensitivity G6PD Taking ACE inhibitor

Intervention groups
1. 30 patients :40 mg of methylprednisolone acetate in a volume of 1 ml 2. 30 patients: 3 cc of platelets with a concentration of 4-6 times that of blood platelets resulting from two rounds of centrifugation containing leukocyte poor plasma without adding activators. 3. 30 patients:10 ml of ozone with a concentration of 15 micrograms per ml

Main outcome variables
lateral epicondyle pain/ patient's daily living performance /Pain pressure threshold

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130523013442N35**
Registration date: **2023-11-19, 1402/08/28**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-19, 1402/08/28**
Update count: **0**

Registration date
2023-11-19, 1402/08/28

Registrant information

Name
Seyed Ahmad Raeissadat

Name of organization / entity
Modares Hospital

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2023-11-01, 1402/08/10

Expected recruitment end date

2024-06-30, 1403/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of ultrasound guided injection of Corticosteroid, Platelet-rich Plasma(PRP), and Ozone on pain and function of patients with lateral epicondylitis: A multicenter randomized clinical trial

Public title

Comparison of the Efficacy of ultrasound guided injection of Corticosteroid, Platelet-rich Plasma(PRP), and Ozone on pain and function of patients with lateral epicondylitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with treatment-resistant tennis elbow duration of 3 months or more pain intensity of VAS 5 or more age of 20 to 50 years

Exclusion criteria:

Symptoms of an infectious disease or fever in the last few days Thyroid dysfunction or uncontrolled diabetes Rheumatic disease History of hematologic or bone malignancy Elbow joint injury Carpal tunnel syndrome and other peripheral nerve injuries including radial nerve injury Cervical radiculopathy that affects the Mayo questionnaire History of autoimmune disease Platelet disorder Treatment with antiplatelet drugs in the last 10 days Platelets below 150,000 Treatment with non-steroidal anti-inflammatory drugs within 48 hours before injection Steroid use in the past 3 weeks Hemoglobin below 10 History of vasovagal shock Pregnancy or breastfeeding Treatment of lateral epicondylitis with steroids in the last 6 months Lateral epicondylitis surgery Ozone sensitivity G6PD Taking ACE inhibitor

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

in this clinical trial study, 90 patients with a diagnosis of lateral epicondylitis will be included in the study randomly .For random allocation of individuals in the study groups (intervention or intervention group and comparison or comparison group), the method of random allocation with block method (Block Randomization) will be used In this method, blocks with size of six (including three people in the intervention group and three people in the comparison group) with a ratio of 1: 1 will be used. Random Allocation software 2.0 will be used to generate random sequences. For concealment, the random allocation concealment method is used in such a way that random sequences are created. In this method, they are identified with two type of cards which are including group a (1st intervention group), b (2nd intervention group) and c (control group) and these cards are placed inside the sealed envelopes in order .In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then, according to the order of entry of the eligible participants, the envelopes will be opened and the assigned group of the participant will be determined. Due to the multicenter nature of this study, the randomization of the study subjects will be performed separately in each center.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, all patients, caregivers, responsible for data collection, examiner are all unaware of the intervention performed for included participants. To blind the examiner, the injection syringes will be covered. Patients will be randomly assigned to the intervention groups and will not be aware of the injected substance used.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.SBMU.MSP.REC.1401.645

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 in lateral epicondyle
Timepoint
At the beginning of the study (before the start of the intervention) and 2 months and 6 months after the intervention
Method of measurement
Visual analogue scale (VAS)

2

Description
pain pressure thresold
Timepoint
At the beginning of the study (before the start of the intervention) and 2 months and 6 months after the intervention
Method of measurement
Algometer

3

Description
patient's performance
Timepoint
At the beginning of the study (before the start of the intervention) and 2 months and 6 months after the intervention
Method of measurement
Mayo questionnaire score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 patients with lateral epicondylitis who are injected with 10 ml of ozone with a concentration of 15 µg/ml under ultrasound guidance.
Category
Treatment - Drugs

2

Description
Intervention group: 30 patients with lateral epicondylitis who are injected with 3 cc of platelets under ultrasound guidance. with a concentration of 4-6 times that of blood platelets resulting from two rounds of centrifugation (first 12 minutes at 1600 rpm and the next round at 7 minutes at 3500 rpm) containing leukocyte poor plasma without adding activators
Category
Treatment - Drugs

3

Description
Control group: 30 patients with lateral epicondylitis who are injected with 40 mg of methylprednisolone acetate in a volume of 1 ml under ultrasound guidance.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mosarres Hospital
Full name of responsible person
Seyed Ahmad Raeissadat
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Shahid Modarres hospital , Kaj Square, Sa'adat abad
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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Modava pain clinic,5th floor, number 6, Golban St,Tarbiat Moalem St,Farahzadi Blvd,Shahrak Qarb St,Tehran
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Sponsors / Funding sources

1

Sponsor
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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
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
Mahfam pourazin
Position
Resident of Physical medicine and Rehabilitation
Latest degree
Medical doctor
Other areas of specialty/work
Physical Medicine
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Person responsible for updating data

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mahfampourazin@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not 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
All the data of people participating in this study can be shared after deidentifying people

When the data will become available and for how long
The access period starts one year after the results are published

To whom data/document is available
Data of this study will be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used
If the goal of the researchers is to conduct a systematic review and meta-analysis on the data, the non-identifiable data of the patients will be provided to the researchers.

From where data/document is obtainable
By sending an email to mahfampourazin@gmail.com

What processes are involved for a request to access data/document
Sending an e-mail and explaining the purpose and how to use the data

Comments