Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effect of Local Injection of Ozone and Corticosteroid and Prolotropics Under Sonography on Elbow Syndrome Tennis Players (TB): A Multi-centered Double-Blind Randomized Clinical Trial

Protocol summary

Study aim
The effect of Sono-guided Oxygen-ozone/ corticosteroid and prothorectropy local injection in the treatment of of Tennis Elbow Syndrome (Elbow Tennis).

Design
A phase 3, umulticenteral, randomized, positive controlled, double blinded, clinical trial with a parallel group design of 75 patients (25 in each group), followed up one week and two months after injection

Settings and conduct
Department of Physical Medicine and Rehabilitation of Shohada Hospital and Imam Reza Hospital affiliated to Tabriz University of Medical Sciences and Physiotherapy and Rehabilitation Physics Department of Rasoul Akram Medical Center affiliated to Iran University of Medical Sciences

Participants/Inclusion and exclusion criteria
pain in the outer part of the ear for a month, Localized tenderness in the external articular region (at the site of the forearm extensors), Exacerbation of pain during supination on the back of the head while maintaining flexion, Resilience during the dorsiflexion of the wrist against resistance, Exacerbation of pain along with pushing along with the pressure of the hand; Having symptoms for more than 4 weeks or history of trauma to the elbow, A history of connective tissue disease or diffuse pain syndrome (such as fibromyalgia, chronic pain syndrome), Inflammatory arthropathy, Use of previous treatments for external epicondylitis, Failure to create heavy tasks, The presence of radiculopathy, Complete rupture of tendon radialis brevis extensor 9- Efficacy in the area of austerity, Use anticoagulants, Existing Injection Detection.

Intervention groups
Topical ozone injection group: 2cc ozone 20µg/L Corticosteroid injection group: 1cc triamcinolone 40mg + 1cc normal slain and prolotherapy group: 2cc dextrose 50%

Main outcome variables
Visual Analogue Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151017024572N16**
Registration date: **2018-06-24, 1397/04/03**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-24, 1397/04/03**
Update count: **0**

Registration date
2018-06-24, 1397/04/03

Registrant information

Name
Arash Babaei-Ghazani

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-08-23, 1396/06/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Effect of Local Injection of Ozone and Corticosteroid and Prolotropics Under Sonography on Elbow Syndrome Tennis Players (TB): A Multi-centered Double-Blind Randomized Clinical Trial

Public title
Evaluation of the Effect of Local Injection of Ozone and Corticosteroid and Prolotropics Under Sonography on Treatment of Tennis Elbow Syndrome (Elbow Tennis)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Anxiety in the outer part of the ear for a month Localized tenderness in the external region of the armpit (at the point of attachment of the extensors of the forearm) Exacerbation of pain during supination on the back of the head while maintaining flexion. Exacerbation of pain during dorsiflexion of the wrist against resistance Exacerbation of pain as well as punching along with the pressure of the hand
Exclusion criteria:
There are symptoms for more than 4 weeks or history of trauma to the elbow - History of connective tissue disease or diffuse pain syndrome (such as fibromyalgia, chronic pain syndrome - Inflammatory arthropathy - Use of previous therapies for external epicondylitis - The possibility of creating heavy work Full Radiolysis Brevis Extension Cardiac Tendon Radiculopathy Full Radiolysis Brevis Extension Cardiac Tendon Aphrodisiac Taking anticoagulants Existing Injection Detection
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple random method for randomization will be used and individuals (patients) will form random units. A random sequence will be generated using RAS software. A central randomization method will be used to conceal random allocation. The random sequence will be created by the statistician and will be available to her. The doctor will be connected to the statistician by telephone or text message and will ask him or her about the random allocation of the participant to the specific group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This randomized, double-blind randomized clinical trial is a multi-centered patient with a positive control group and will be performed in four groups of patients with musculoskeletal disorders by four physicians and physicians in four different health centers. All patients will be given enough information about the properties of ozone and corticosteroid injections, possible side effects, method and duration of testing, and the likelihood of having a candidate from one of the two treatments. All patients will be asked to sign a written informed consent form.In order to blind the patient, the doctor will prepare the injection material in the syringe, and will cover the syringes with an aluminum sheet to avoid being aware of the type of injection. It should be noted that dilution of corticosteroid and normal salon will be done to equalize the volume of all three injectable solutions. Patients in each group will be evaluated by a physical medicine and rehabilitation specialist who is not aware of the type of injection, before the injection, one week after the injection and two months after the injection, and the rate of change between the two groups will be compared at different times. It should be noted that in each center all injections are performed by a constant person (a physical medicine and rehabilitation specialist). Using three-flood coded questionnaires, where the first flood represents the group, the second flood indicates the time of the measurement of the outcome and the third flood represents the patient's code, the analyst will also be unaware of the allocation of people to the treatment groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-06-22, 1396/04/01

Ethics committee reference number
IR.IUMS.REC1396.30323

Health conditions studied

1

Description of health condition studied
Tennis player elbow syndrome
ICD-10 code
G59
ICD-10 code description
Mononeuropathy in diseases classified elsewhere

Primary outcomes

1

Description
Pain
Timepoint
Before injection, 2 weeks and 8 weeks after injection
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Clinical Global Impression
Timepoint
Before injection, 1 weeks and 8 weeks after injection
Method of measurement
Clinical Global Impression Questionnaire

2

Description
Patient Global Impression of Improvement
Timepoint
Before injection, 1 weeks and 8 weeks after injection
Method of measurement
Patient Global Impression of Improvement Questionnaire

3

Description
Tennis Elbow Evaluation
Timepoint
Before injection, 1 weeks and 8 weeks after injection
Method of measurement
Patient-rated Tennis Elbow Evaluation (PRTEE) Questionnaire

4

Description
Extensor tendon thickness
Timepoint
Before injection, 1 weeks and 8 weeks after injection
Method of measurement
Sonography

Intervention groups

1

Description
Intervention group (ozone therapy): 2cc ozone 20µg / L, at the joint of the common extensor tendon under ultrasound guidance.
Category
Treatment - Drugs

2

Description
Intervention group (porlotherapy): 2cc dextrose 50%, at the joint of the common extensor tendon under ultrasound guidance.
Category
Treatment - Drugs

3

Description
Control group (corticosteroid therapy): 1cc triamcinolone 40mg + 1cc normal slain, at the joint of the common extensor tendon under ultrasound guidance.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Physical Medicine and Rehabilitation of Rasoul-e-Akram Medical Education Center affili
Full name of responsible person
Arash Babaie
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2

Recruitment center
Name of recruitment center
Physical medicine and rehabilitation research center of Imam Reza Hospital affiliated to Tabriz Univ
Full name of responsible person

Dr. Babak Kolahi

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3

Recruitment center

Name of recruitment center
Physical medicine and rehabilitation research center of Shohada Hospital affiliated to Tabriz Univer

Full name of responsible person
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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
Tabriz University of Medical Sciences

Proportion provided by this source
70

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

2

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Seyed Kazem Malakouti

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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
Iran University of Medical Sciences

Proportion provided by this source
30

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
Iran University of Medical Sciences

Full name of responsible person
Dr. Arash Babaei

Position
Associate Professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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