

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluation of the Effect of Local Injection of Ozone and Corticosteroid and Prolotherapy 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 prolotherapy local injection in the treatment of Tennis Elbow Syndrome (Elbow Tennis).

Design

A phase 3, multicenter, 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 elbow 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 hand 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 austerit, Use anticoagulants, Existing Injection Detection.

Intervention groups

Topical ozone injection group: 2cc ozone 20µg/L
Corticosteroid injection group: 1cc triamcinolone 40mg + 1cc normal saline 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

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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 Prolotherapy 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 Prolotherapy 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 saline 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-fold 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**

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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 20 μ g / 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 saline, 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

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Full name of responsible person

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3

Recruitment center

Name of recruitment center
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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

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Iran University of Medical Sciences
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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
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Full name of responsible person
Dr. Arash Babaei
Position
Associate Professor of Physical Medicine and
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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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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