

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Arash Babaei-Ghazani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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**

Iran University of Medical Sciences

**Street address**

Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences

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**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 20 $\mu$ 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

##### Street address

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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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Imam Reza hospital, University Ave.  
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### 3

#### **Recruitment center**

**Name of recruitment center**  
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of Shohada Hospital affiliated to Tabriz Univer  
**Full name of responsible person**  
Dr. Bina Eftekharsaadat  
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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Dr. AbolGhasem Joyban  
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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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**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

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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