

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the difference in the effect of platelet-rich plasma (PRP) injection using the Peppering and single injection techniques on pain and function in patients with elbow extensor tendinopathy: A randomized, double-blind clinical trial

#### Protocol summary

##### Study aim

Peppering vs. Single PRP Injection for Pain and Function in Lateral Epicondylitis"

##### Design

A double-blind randomized clinical trial on 34 patients with wrist injury, comparing the effects of PRP injection using Peppering and Single techniques alongside standard treatments on symptom relief and wrist function

##### Settings and conduct

Study location: Sports Medicine Department, Sina Hospital 3-4 mL of PRP was prepared from brachial artery blood by single-spin centrifugation. Patients were seated, elbow at 90°, forearm in pronation. 2 mL of 2% lidocaine was injected subcutaneously. Peppering: PRP injected in multiple directions at the point of maximal tenderness. Single: PRP injected only at the point of maximal tenderness. Patients were observed for 30 min, advised 48-hour rest, acetaminophen as needed, and no anti-inflammatories for 2 weeks. Outcomes (NRS, PRTEE, pressure pain threshold, hand grip) were measured at baseline, 4 and 8 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion: Age 18-60, lateral elbow tendinopathy, pain  $\geq 2/10$  NRS. Exclusion: Upper limb/neck surgery/injury, recent whiplash/fibromyalgia/cervical stenosis, chronic inflammatory/neuro-psychiatric disease, recent physio/acupuncture/chiropractic, nerve compression, bleeding disorder/NSAID/steroid use, pregnancy

##### Intervention groups

Group 1: PRP via Peppering + Counterforce brace + wrist extensor stretching Group 2: PRP via Single + Counterforce brace + wrist extensor stretching

##### Main outcome variables

Determining the effect of PRP injection by Peppering method versus single in the lateral epicondyle on pain

symptoms and function in patients with acute elbow extensor tendinopathy./ Determining the effect of PRP injection by Peppering method versus single on wrist strength/NRS scale for lateral elbow pain/Function by Patient Related Tennis Elbow Evaluation or PRTEE/Pain pressure threshold

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251027067789N1**

Registration date: **2025-12-13, 1404/09/22**

Registration timing: **prospective**

Last update: **2025-12-13, 1404/09/22**

Update count: **0**

##### Registration date

2025-12-13, 1404/09/22

##### Registrant information

##### Name

Bahareh Golestani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3454 1905

##### Email address

golestani\_b@razi.tums.ac.ir

##### Recruitment status

**recruiting**

##### Funding source

##### Expected recruitment start date

2025-12-22, 1404/10/01  
**Expected recruitment end date**  
2026-11-22, 1405/09/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the difference in the effect of platelet-rich plasma (PRP) injection using the Peppering and single injection techniques on pain and function in patients with elbow extensor tendinopathy: A randomized, double-blind clinical trial

**Public title**  
Evaluation of the difference in the effect of platelet-rich plasma (PRP) injection using the Peppering and single injection techniques on pain and function in patients with elbow extensor tendinopathy: A randomized, double-blind clinical trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Pain or tenderness to touch over the lateral epicondylitis and the insertion site of the extensor tendons Pain with gripping a hand dynamometer The pain may be aggravated by stretching or contracting the wrist extensors. At least a score of 2 on the NRS scale from 0 to 10.

**Exclusion criteria:**

Have a history of surgery on the upper limb. Have had surgery related to the cervical spine. Have a history of elbow dislocation or elbow fracture or tendon rupture Have a history of whiplash injury within the past 6 weeks. Have a history of fibromyalgia Have a history of cervical canal stenosis History of chronic inflammatory disease such as: lupus - rheumatoid arthritis - psoriasis Failure to participate in physical therapy, acupuncture, or chiropractic in the past 3 months Having symptoms of nerve compression, such as weakness of upper limb muscles, decreased deep reflexes in the upper limb, and decreased sensation Central nervous system involvement, such as MS Neurological \_ Psychiatric or cognitive disorders and pregnancy The presence of any contraindications for physical therapy, such as skin wounds, infections, and malignancies Absence of a bleeding disorder No use of NSAIDs, steroids, or aspirin within the previous week

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **34**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The distribution of volunteers will be done by random block design with variable blocks of two, four or six (one group with the symbol A and the other group with the symbol B) and using the random number table of the Random allocation software. The sample allocation ratio will be 1:1 and volunteers will be randomly assigned to one of the two injection groups, Single and Peppering.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

This study was conducted as a randomized, double-blind clinical trial. Both participants and outcome assessors were blinded to the type of intervention. To maintain blinding, all injections were performed behind a sterile drape and out of the patient's visual field, using identical syringes, equipment, and a uniform local anesthesia protocol in both groups. The duration of the procedure was also standardized to avoid any perceptible differences between the two injection techniques. All injections were performed by a single physician who, due to the inherent differences between the Peppering and Single techniques, was aware of the allocation but had no role in patient assessment or data collection. Outcome measures, including the Numerical Rating Scale (NRS), the Patient-Rated Tennis Elbow Evaluation (PRTEE), grip strength, and Pain Pressure Threshold (PTT), were recorded by an independent assessor blinded to group assignment. Participants were randomized into two groups in a 1:1 ratio using sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. The success of blinding was evaluated during follow-up by directly asking both participants and assessors to guess the assigned group. Unblinding was allowed only in cases of medical necessity and was fully documented.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Sina Hospital - Tehran University of Medical Sciences (Research Ethics Committee)

**Street address**

Sina Hospital, Hasanabad Square, Imam Khomeini street

**City**

Tehran  
**Province**  
Tehran  
**Postal code**  
۱۴۱۹۷۳۳۱۴۱  
**Approval date**  
2025-05-25, 1404/03/04  
**Ethics committee reference number**  
IR.TUMS.SINAHOSPITAL.REC.1404.026

## Health conditions studied

### 1

#### **Description of health condition studied**

Lateral elbow extensor tendinopathy

#### **ICD-10 code**

M77.1

#### **ICD-10 code description**

Lateral epicondylitis

## Primary outcomes

### 1

#### **Description**

Pain intensity

#### **Timepoint**

It is being evaluated 4 and 8 weeks after injection.

#### **Method of measurement**

Pain intensity will be assessed using the Numerical Rating Scale (NRS), which ranges from 0 to 10, where 0 represents "no pain" and 10 represents "the worst possible pain."

### 2

#### **Description**

Grip strength

#### **Timepoint**

It is being evaluated 4 and 8 weeks after injection.

#### **Method of measurement**

Grip strength will be measured using a hand-held dynamometer, which quantifies the maximum force exerted by the participant's grip.

### 3

#### **Description**

The Pressure Pain Threshold

#### **Timepoint**

It is being evaluated 4 and 8 weeks after injection.

#### **Method of measurement**

The Pressure Pain Threshold (PPT) will be measured using an algometer, a device that applies gradual pressure to a specific point on the body. The participant will report when the pressure becomes painful.

### 4

#### **Description**

The Patient-Rated Tennis Elbow (PRTE) questionnaire

## **Timepoint**

It is being evaluated 4 and 8 weeks after injection.

## **Method of measurement**

The Patient-Rated Tennis Elbow (PRTE) questionnaire evaluates the severity of symptoms and functional limitations caused by tennis elbow. It uses a Likert scale (0-10) for scoring, where 0 means "no pain" or "no difficulty," and 10 represents "worst possible pain" or "unable to perform the activity. Its subscales include 1. Pain Subscale : Measures pain intensity during rest and specific activities. 2. Function Subscale: Assesses limitations in daily activities and work tasks. 3. Impact on Quality of Life

## Secondary outcomes

empty

## Intervention groups

### 1

#### **Description**

First intervention group: Injection of platelet-rich plasma (PRP) produced by a kit manufactured by Celltech Biogen using the pepping method along with conventional treatments including Counterforce brace and wrist extensor stretching exercises

#### **Category**

Treatment - Other

### 2

#### **Description**

Second Intervention group: Injection of platelet-rich plasma (PRP) produced by a kit manufactured by Celltech Biogen Company using a single injection method along with conventional treatments including Counterforce brace and wrist extensor stretching exercises.

#### **Category**

Treatment - Other

## Recruitment centers

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Sina Hospital

##### **Full name of responsible person**

Bahareh Golestani

##### **Street address**

Sina Hospital, Hasanabad Square, Imam Khomeini Street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1136746911

##### **Phone**

+98 21 6634 8500

**Fax**

+98 21 6634 8587

**Email**

hosp\_sina@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Ramin Kordi

**Street address**

Vice Chancellor for Research and Technology, 6th Floor, Central Building of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

**City**

Tehran

**Province**

Tehran

**Postal code**

1416753955

**Phone**

+98 21 8163 3698

**Email**

vcr@tums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Bahareh Golestani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

**Street address**

Sina Hospital, Hasanabad Square, Imam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

5395514176

**Phone**

+98 21 6491 0700

**Email**

golestani\_b@razi.tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Abolhasani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

Sina Hospital, Hasanabad Square, Imam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

5395514176

**Phone**

+98 21 6491 0700

**Email**

maryam.abolhasani@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Bahareh Golestani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

**Street address**

Sina Hospital, Hasanabad Square, Imam Khomeini street

**City**

Tehran

**Province**

Tehran

**Postal code**

5395514176

**Phone**

+98 21 6491 0700

**Email**

golestani\_b@razi.tums.ac.ir

**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**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable