Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of the difference in the effect of platelet-rich plasma (PRP) injection using the Peppering ands 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 ≥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

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Bahareh Golestani
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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 ands 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 ands 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 peppering 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

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Sponsors / Funding sources

1

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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

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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

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