

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparing the effects of Platelet-rich plasma (PRP) with Corticosteroid injection in resistant tennis Elbow patients to non-surgical treatment

#### Protocol summary

##### Study aim

Comparing the effects of Platelet-Rich Plasma with Corticosteroid injection in resistant tennis elbow patients to Nonsurgical treatment

##### Design

Two arm parallel group randomised trial without blinded postoperative care and outcome assessment. sampling size is 36 patients that is divided to 2 group of 18 patients

##### Settings and conduct

Shahid Madani academic medicinal center

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with lateral epicondylitis and related functional impairments diagnosed. That is patients who after six weeks of \*non - surgical care such as resting, avoiding severe activities, Behavior reform, physical therapy, Non Steroid Anti Inflammatory Drug (NSAID) by resisted wrist extension test in forearm pronation and elbow extension VAS score=5 or more symptoms lasting for at least 3 months Exclusion criteria: Age of 70 years old or more History of infectious diseases or fever in recent days History of any malignancies Diagnosed carpal tunnel syndrome or any other peripheral nerve lesions or cervical radiculopathy Systemic diseases such as ischemic heart disease, diabetes mellitus, rheumatoid arthritis or hepatitis Any bone malformations or bone injuries in humerus or elbow joint History of autoimmune diseases History of Platelet dysfunction using anti platelet medications during last 10 days or using NSAIDs during last 48 hours before injection Using steroids during last 3 weeks Hb=10 or less patients with platelet count less than 150000 History of vasovagal reaction Pregnancy or breast feeding

##### Intervention groups

The injection of 40 mg of Prednisolone acetate in the control group and the injection of two mL of Platelet - Rich Plasma obtained from the patient's blood centrifuge (intervention group)) at the maximum tenderness point in the peppering method

#### Main outcome variables

Pain: function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191105045335N1**

Registration date: **2020-05-29, 1399/03/09**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-29, 1399/03/09**

Update count: **0**

##### Registration date

2020-05-29, 1399/03/09

##### Registrant information

##### Name

Fatemeh Ochi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3350 9825

##### Email address

lamy@chmail.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-21, 1399/03/01

##### Expected recruitment end date

2021-05-22, 1400/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparing the effects of Platelet-rich plasma (PRP) with Corticosteroid injection in resistant tennis Elbow patients to non-surgical treatment

**Public title**

Comparing the effects of Platelet-rich plasma (PRP) with Corticosteroid injection in resistant tennis Elbow patients to non-surgical treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients diagnosed with lateral epicondylitis and related functional impairments after six weeks of \*non - surgical care such as resting, avoiding severe activities, Behavior reform, physical therapy, Non Steroid Anti Inflammatory Drug (NSAID) In physical examination, resisted wrist extension test in forearm pronation and elbow extension, VAS score=5 or more symptoms lasting for at least 3 months

**Exclusion criteria:**

Age of 70 years old or more History of infectious diseases or fever in recent days History of any malignancies Diagnosed carpal tunnel syndrome or any other peripheral nerve lesions or cervical radiculopathy Systemic diseases such as ischemic heart disease, diabetes mellitus, rheumatoid arthritis or hepatitis Any bone malformations or bone injuries in humerus or elbow joint History of autoimmune diseases History of Platelet dysfunction using anti platelet medications during last 10 days or using NSAIDs during last 48 hours before injection Using steroids during last 3 weeks Hb=10 or less patients with platelet count less than 150000 History of vasovagal reaction Pregnancy or breast feeding

**Age**

To **70 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are divided into two groups based on random numbers. In (random digits table) the numbers are rounded up to 9 in row and columns. The order to extract and adjust these numbers is made entirely by the computer.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Alborz University of Medical Sciences

**Street address**

Deputy of research and technology ,Shahid Saffarian Ave, Golshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

3198764653

**Approval date**

2020-02-15, 1398/11/26

**Ethics committee reference number**

IR.ABZUMS.REC.1399.036

**Health conditions studied****1****Description of health condition studied**

Lateral epicondylitis

**ICD-10 code**

M77.1

**ICD-10 code description**

Lateral epicondylitis

**Primary outcomes****1****Description**

pain

**Timepoint**

before injection, 2week ,1 and 3 months after injection

**Method of measurement**

Visual analogue scale (VAS)

**2****Description**

function

**Timepoint**

before injection, 2week ,1 and 3 months after injection

**Method of measurement**

Disabilities of the Arm, Shoulder and Hand (DASH) score

## Secondary outcomes

### 1

#### Description

side effects of injection

#### Timepoint

2week,1 and 3 months after injection

#### Method of measurement

Clinical examination

## Intervention groups

### 1

#### Description

Intervention group: the injection of two mL Platelet - Rich Plasma, obtained from the patient's blood centrifuge, at the maximum tenderness point by peppering method.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The injection of 40 mg of Prednisolone acetate at the maximum tenderness point using peppering method.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Madani hospital

##### Full name of responsible person

Salman Azarsina

##### Street address

Jahanshahr

##### City

Karaj

##### Province

Alborz

##### Postal code

3198688381

##### Phone

+98 26 3441 2841

##### Email

azarsina1@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Mohammad Noori Sepehr

#### Street address

Deputy of research and technology ,Shahid Saffarian Ave, Golshahr

#### City

Karaj

#### Province

Alborz

#### Postal code

3198764653

#### Phone

+98 26 3464 3705

#### Email

dr.noorisepehr@abzums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Karaj 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

Karaj University of Medical Sciences

##### Full name of responsible person

Fatemeh Ochi Ardebili

##### Position

Student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

No,74-Shahid Ali Hatami Ave-Golshahr

##### City

Karaj

##### Province

Alborz

##### Postal code

3198688381

##### Phone

+98 26 3350 9825

##### Email

lamy@chmail.ir

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Arvin Najfi

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Shahid Madani hospital-Jahanshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

3198688381

**Phone**

+98 26 3441 2841

**Email**

Parsmedicine@gmail.com

## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Fatemeh Ochi Ardebili

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

No,74-Shahid Ali Hatami Ave-Golshahr

**City**

Karaj

**Province**

Alborz

**Postal code**

3198688381

**Phone**

+98 26 3350 9825

**Email**

lamy@chmail.ir

## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available