# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Study of the long term effects of local Platelet-rich plasma (PRP) injection versus Autologous blood injection in patients with Lateral Epicondylitis in PM & R clinic of Modarres Hospital from 2011 to 2013

## Protocol summary


**Summary**

Chronic lateral elbow epicondylitis known as tennis elbow is an angiofibrolastic tendinosis involving the origin of wrist extensor muscles. Healing of this lesion is reported with the use of Autologous whole blood (AWB) and Platelet-rich plasma (PRP). We conducted this study to compare the effects of PRP with AWB local injection in patients with chronic tennis elbow.Fifty five patients with chronic lateral epicondylitis with duration of symptoms more than 3 months were randomly divided into 2 groups. Group 1 subjects received a single injection of 2mL of Autologous PRP and group 2 injected with 2mL of Autologous blood. Tennis elbow strap, stretching and strengthening exercises were administered for both groups during 2 month follow up. Pain and functional improvements were assessed using visual analog scale (VAS), Modified Mayo Clinic Performance Index (MMCPI) for the elbow and pressure pain threshold (PPT) at baseline and then at the end of 1,2,6 and 12months.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013100513442N3**
Registration date: **2013-11-05, 1392/08/14**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2013-11-05, 1392/08/14

**Registrant information**


**Name**

Seyed Ahmad Raeissadat

**Name of organization / entity**

Modares Hospital

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2273 1112

**Email address**

a_raeissadat@sbmu.ac.ir


**Recruitment status**

**Recruitment complete**


**Funding source**

Faculty of Medicine, Shahid Beheshti University of Medical Sciences


**Expected recruitment start date**

2012-01-21, 1390/11/01

**Expected recruitment end date**

2012-08-22, 1391/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Study of the long term effects of local Platelet-rich plasma (PRP) injection versus Autologous blood injection in patients with Lateral Epicondylitis in PM & R clinic of Modarres Hospital from 2011 to 2013

**Public title**

Study of the long term effects of local Platelet-rich plasma (PRP) injection versus Autologous blood injection in patients with Lateral Epicondylitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: history of chronic (at least 3months) pain or swelling of the lateral epicondyle and pain more

than 5 of 10 according to visual analogue scale. Exclusion criteria: systemic disorders such as diabetes, Rheumatoid Arthritis; hematological diseases (coagulopathy); severe cardiovascular diseases; infections; immunosuppression; patients in therapy with anticoagulants or antiaggregants; the use of NSAIDs in the 2 days before blood donation; patients with Hb values of 10; platelet values of 100,000/mmc; Pregnancy; vasovagal shock; injection of corticosteroid in since 2 weeks ago; any injection in site of tenderness since 1 month ago; malignancy; history of CTS; cervical radiculopathy; radial neuropathy.

**Age**
To **75 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **55**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethic Committe of Faculty of Medicine, Shahid Beheshti University of Medical Sciences

**Street address**
Shahid Beheshti University of Medical Sciences, Yaman St, Shahid Chamran Highway, Tehran,Iran

**City**
Tehran

**Postal code**

**Approval date**
2010-08-20, 1389/05/29

**Ethics committee reference number**
12007

## 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**
0,1,2,6,12 months

**Method of measurement**
VAS Questionnaire

## Secondary outcomes

### 1

**Description**
elbow function

**Timepoint**
0,1,2 ,6,12 months

**Method of measurement**
Modified Mayo clinic performance index for the elbow Questionnaire

## Intervention groups

### 1

**Description**
Tennis Elbow strap and wrist extensor strengthening exercises,2/day and 5times for each exercise and wrist extensors stretching exercises,2/day and 30sec for each exercise and 500mg/8h Acetaminophen PRN and an injection of 2cc autologous blood in control group

**Category**
Treatment - Drugs

### 2

**Description**
Tennis Elbow strap and wrist extensor strengthening exercises,2/day and 5times for each exercise and wrist extensors stretching exercises,2/day and 30sec for each exercise and 500mg/8h Acetaminophen PRN and an Injection of 2cc PRP in intervention group

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Modarres Hospital

**Full name of responsible person**

Rosa Rahimi

**Street address**

Saadat Abad, Yadegar e Emam Highway, Tehran, Iran

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Ethic Committe of Faculty of Medicine,Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Vice chancellor for research, Dr. Rahmati Roodsari

**Street address**

Shahid Beheshti University of Medical Siences, Yaman St, Shahid Cjamran High Way, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Ethic Committe of Faculty of Medicine,Shahid Beheshti University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Shahid Modarres Hospital

**Full name of responsible person**

Rosa Rahimi

**Position**

Resident

**Other areas of specialty/work**

**Street address**

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**City**

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**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Modarres Hospital

**Full name of responsible person**

Seyed Ahmad Raeissadat

**Position**

Assistant Professor

**Other areas of specialty/work**

**Street address**

Shahid Modarres Hospital, SaadatAbad, Tehran, Iran

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**Phone**

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a_raeissadat@sbmu.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*