Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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

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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

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

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Person responsible for scientific inquiries

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Seyed Ahmad Raeissadat

Position

Assistant Professor

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Email

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