

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

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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

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

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inquiries

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Arvin Najfi

Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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