

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Studing of the effect of platelet rich plasma versus corticosteroid injection on pain and function of patients with lateral epicondylitis

Protocol summary

Study aim

comparison of the effect of corticosteroid and platelet rich plasma injection on pain and function of patients with lateral epicondylitis

Design

In this study, 44 patients diagnosed with lateral epicondylitis in PM&R clinic of Shahid Modarres hospital will be randomly allocated to two groups of 22 patients. Randomization will be done by the means of random number generated by computer. Injection of PRP in the intervention group or steroid in the control group will be performed. This is a phase 2-3 clinical trial in which the effect of PRP injection in treatment of lateral epicondylitis and comparison it with corticosteroid injection will be studied.

Settings and conduct

In this study ,which will be conducted in Shahid Modarres hospital inTehran, patients diagnosed with lateral epicondylitis will be randomly allocated to two groups of 22 patients based on the random numbers generated by computer, and will be injected either with steroid or PRP. unfortunately, because of blood obtaining procedure in PRP group, blinding of patients is not possible in this trial. In steroid injection group, 40mg methylprednisolone acetate and in PRP injection group 2cc of PRP, obtained from centrifuge of patients blood, will be injected in maximum point of tenderness with peppering technique. The outcome of intervention will be measured by three scales. Pain will be assessed by visual analogue scale and pressure pain threshold and function will be measured by Modified Mayo clinic performance index for elbow. These measurements will be done before injection, 2 and 6 months after injections and results will be compared among groups. The goal of this study is to evaluate pain reduction and function improvement in each group and comparison of two groups in this regard. Also, incidence of complications in each group will be studied and compared with the other group.

Participants/Inclusion and exclusion criteria

Patients diagnosed with lateral epicondylitis by means of physical examination who has been suffering from symptoms for more than 3 months and their pain score is more than 5 in visual analogue scale will be included in this study. The exclusion criteria are age of 70 years or more; systemic diseases; diseases in which the symptoms may overlap with patients symptoms for example radiculopathy or peripheral nerve lesions; blood cell count disorders; autoimmune diseases; malignancies or infectious diseases; using medications that interfere with platelet function or steroids; pregnancy or breast feeding.

Intervention groups

In PRP group, first 20cc of patient's blood will be obtained and centrifuged for 15 minutes with 1600 rpm to separete platelets from erythrocytes and then centrifuged with 2800rpm for 7 minutes to concentrate the platelets. 8 minutes after being prepped and draped and injected by 2cc of Lidocaine 1%, the point of maximum tenderness will be injected by 2cc of leukocyte rich PRP with peppering technique, via a needle of gauge 22. in corticosteroid injection group, 40mg of methylprednisolone acetate with a volume of 1 cc will be injected in maximum point of tenderness by a 22G needle with peppering technique, 8 minutes after prepping and injecting this point with 2cc of Lidocaine 1%. No kinds of steroids or NSAIDs will be prescribed during follow up period. To reduce pain, only Paracetamol will be used along with ice. Patients of both groups will be requested to refrain from heavy labor activities for a week. Tennis elbow strap will be administered for all patients and they will be instructed to apply the strap 2 centimeters below the maximal tenderness point at elbow. Therapeutic exercises will be taught by a PM&R resident and instructions will be provided in writing to help patients do the exercises correctly. 3 days after injection patients will be asked to begin stretching of extensor muscles and two weeks after injection, eccentric exercises will begin twice daily for 5 weeks and after 4 weeks, the patient can return to daily activities with no restrictions.

Main outcome variables

Outcomes will be measured by 3 means, pain will be measured subjectively by VAS score, and objectively algometer device will measure the pressure pain threshold. Function will be evaluated by means of Modified Mayo clinic performance index for elbow score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N16**

Registration date: **2017-11-28, 1396/09/07**

Registration timing: **registered_while_recruiting**

Last update: **2017-11-28, 1396/09/07**

Update count: **0**

Registration date

2017-11-28, 1396/09/07

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2273 1112

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a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

This study is funded by the PM&R department of SBUMS.

Expected recruitment start date

2017-08-11, 1396/05/20

Expected recruitment end date

2017-12-11, 1396/09/20

Actual recruitment start date

2017-08-11, 1396/05/20

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying of the effect of platelet rich plasma versus corticosteroid injection on pain and function of patients with lateral epicondylitis

Public title

comparison of the effect of PRP versus corticosteroid injection in treatment of tennis elbow

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with lateral epicondylitis and related functional

impairments diagnosed 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

Age

To **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **44**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated to two groups of PRP or steroid injection according to random numbers generated by 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 Shahid Beheshti University of medical sciences

Street address

7th floor, Bldg NO.2, Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran
Postal code
1985717443
Approval date
2017-08-08, 1396/05/17
Ethics committee reference number
IR.SBMU.MSP.REC.1396.317

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, 2 and 6 months after injection

Method of measurement

VAS score, Pain pressure threshold

2

Description

function

Timepoint

before injection, 2 and 6 months after injection

Method of measurement

Persian version of modified Myo clinic performane index for elbow

Secondary outcomes

1

Description

Complications of treatment

Timepoint

before injection, 2 and 6 months after injection

Method of measurement

clinical evaluation

Intervention groups

1

Description

Control group: 8 minutes after being prepped and draped and injected by 2cc of Lidocaine 1%, the point of maximum tenderness will be injected by 40mg of methylprednisolone acetate with a volume of 1 cc by a 22G needle with peppering technique.

Category

Treatment - Drugs

2

Description

Intervention group: 8 minutes after being prepped and draped and injected by 2cc of Lidocaine 1%, the point of maximum tenderness will be injected by 2cc of leukocyte rich PRP with peppering technique, via a needle of gauge 22.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Seyed Ahmad Raeissadat

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

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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

Shahid beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Hesam Abdollahzadeh

Position

Resident of Physical medicine and rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

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Full name of responsible person

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Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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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

Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Modarres hospital, Saadat abad Blvd, Tehran

City

make this available