Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 seperate 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
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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
Studing 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 Pregnency 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 Behesthi University of Mecial Sciences, Arabi Ave, Daneshjoo Bvld, 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
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Sponsors / Funding sources

1

Sponsor
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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
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Medical doctor
Other areas of specialty/work
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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

make this available