Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The comparison of the effectiveness of high leukocyte PRP, low leukocyte PRP & placebo in treatment of the patients having rotator cuff tendinopathy or partial tear

Protocol summary

Study aim
Assessment and comparison of the effect of the high leukocyte and low leukocyte plasma rich platelet in the rotator cuff injuries

Design
In this double blinded randomized control group study, a total of 75 patients who have the inclusion criteria will be randomized into the three groups via random numbers table. 25 patients in the high leukocyte platelet rich plasma, 25 patients in the low leukocyte platelet rich plasma and 25 patients in the group subjected to placebo injection will be followed in parallel groups. The patients in the three groups will be subjected to the same therapeutic exercise protocol following the injection. Range of shoulder motion and the strength of the rotator cuff muscles and also pain and disability will be assessed before the treatment and then at 1,3 and 6 months after starting the treatment. Data is entered in the SPSS version 22 software and statistically measured by the use of t-student & Mann-Whitney u tests.

Settings and conduct
Patients with shoulder pain more than 6 weeks are referred to the sports medicine clinic of Rasoul-e-Akram Hospital, they are examined by the sports medical specialist and if tendinopathy or incomplete tear of their Rotator Cuff would be diagnosed by physical exams & confirmed by MRI findings, and If they do not have exclusion conditions, they will be included in the study

Participants/Inclusion and exclusion criteria
Inclusion criteria: Shoulder pain more than six weeks Tendinopathy or partial tear of rotator cuff tendons Exclusion criteria Total tear of rotator cuff The history of shoulder surgery

Intervention groups
Intervention group 1: Platelet rich plasma with high leukocyte; Intervention group 2: Platelet rich plasma with low leukocyte; Control group 3: Placebo injection

Main outcome variables
Patients' pain and function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100718004409N12**
Registration date: **2019-09-28, 1398/07/06**
Registration timing: **retrospective**

Last update: **2019-09-28, 1398/07/06**
Update count: **0**

Registration date
2019-09-28, 1398/07/06

Registrant information

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Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-06-22, 1398/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the effectiveness of high leukocyte PRP, low leukocyte PRP & placebo in treatment of the patients having rotator cuff tendinopathy or partial tear

Public title
The comparison of effectiveness of high leukocyte and low leukocyte PRP in tendinopathy and partial tear of rotator cuff
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Shoulder pain lasted more than 6 weeks At least 3 positive specific shoulder tests MRI findings implying tendinopathy or partial tear of rotator cuff
Exclusion criteria:
Shoulder pain that lasted less than six weeks The presence of sensory or motor disturbances caused by the cervical radiculer pain Evidence from other pathologies that can lead to shoulder pain. For example, the presence of calcified tendonitis or adhesive capsulitis and ... History of shoulder surgery in the last 6 months The presence of inflammatory rhomatologic diseases such as rheumatoid arthritis, fibromyalgia, poly mialia rheumatica and ... Complete rupture of rotator cuff tendons based on MRI findings The presence of ligamentous laxity or shoulder instability based on physical examination History of corticosteroid, analgesic or hyaluronic acid injection in the shoulder joint over the past 3 months History of exercise therapy and physiotherapy modalities over the past 6 weeks The history of treatment with PRP in the last 6 months Use of other therapies during the intervention period Patients request for discontinuing the treatment Contraindications for performing MRI or PRP in patients Any non-rheumatologic inflammatory disease and severe acute infection in patients Thrombocytopenia in patients
Age
From **40 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
The included patients will be randomized in a simple randomization method. The random number tables found in the most statistical text books will be used for the random numbers. The numbers between 0-24 are considered for the first group, 25-49 for the second group and 50 -75 for the third group. The 3 groups are 1- high leukocyte-PRP, 2- low leukocyte PRP & 3- the placebo group. concealment is performed in sequentially numbered, sealed & opaque envelopes, and will be kept by the department secretory.
Blinding (investigator's opinion)
Double blinded
Blinding description
After randomization the patients of the each group will be introduced to the researcher 2 by the researcher 1 for evaluation of the outcomes. The researcher 2 only evaluates the outcomes and records the findings without being informed of the intervention and its effects. The analyzer receives the data at the end of the study and is not informed of the intervention groups at all. The patients are not informed about the injected syringe. Blood of the patients in the three groups will be centrifuged then the plasma in the groups 1 and 2 and the normal saline of the control group will be pulled in a covered syringe injected will be covered.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Iran university of medical sciences
Street address
Iran University of Medical Sciences, Near the Milad Tower,Hemmat highway
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Approval date
2019-05-22, 1398/03/01
Ethics committee reference number
IR.IUMS.FMD.REC.1398.073

Health conditions studied

1

Description of health condition studied
rotator cuff tendinopathy, partial tear of rotator cuff
ICD-10 code
M75.1
ICD-10 code description

Rotator cuff tear or rupture, not specified as traumatic

2

Description of health condition studied
Shoulder impingement
ICD-10 code
M75.40
ICD-10 code description
Impingement syndrome of unspecified shoulder

Primary outcomes

1

Description
pain amount
Timepoint
Before intervention, 1 ,3 ,6 months after intervention
Method of measurement
Visual Analog Scale

2

Description
Function of the patients
Timepoint
Before intervention, 1 ,3 ,6 months after intervention
Method of measurement
WORC & DASH questionnaires

Secondary outcomes

1

Description
Shoulder range of motion
Timepoint
Before the intervention, 1,3,6 months after intervention
Method of measurement
Goniometry

2

Description
Rotator cuff strength
Timepoint
Before the intervention, 1,3,6 months after intervention
Method of measurement
Muscle Manual Test

Intervention groups

1

Description
Intervention group 1: Platelet rich plasma with high leukocyte 20 cc blood will be centrifuged in two 10-minute steps by Rooyagen kit then the 2 cc of the plasma will be drained
Category
Treatment - Other

2

Description
Intervention group: Platelet rich plasma with low leukocyte in this group the 2 cc of plasma will not be drained
Category
Treatment - Other

3

Description
Intervention group 3 or control group: placebo injection 0.5 cc normal saline will be injected in the shoulder
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran university of medical sciences, Rasool hospital,sports medicine clinic
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Sponsors / Funding sources

1

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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
Iran 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

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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
Unawareness of this item
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