

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 radicular 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 secretary.

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

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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