Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Investigating the Role of Platelet-Rich Plasma in Shoulder Rotator Cuff Repair With Arthroscopy

Protocol summary

Study aim

1- evaluation the effect of platelet-rich plasma injection during arthroscopic surgery

Design

The simple random allocation method is that the intervention group (platelet-rich plasma) will be given odd numbers from the beginning, and the control group (without platelet-rich plasma injection) will be given even numbers. Each number is written on a card and placed in an envelope, the envelopes are sealed and the patient's name is written on each envelope. Each patient is given an envelope in order of numbers. Registration of patients and their allocation in each of the groups is done by someone other than the doctor.

Settings and conduct

For one group, PRP injection was performed, and in this method, the patient had one PRP injection during the arthroscopy operation. In this group, 20 cc of venous blood was taken. In this case, 3 cc of liquid containing platelets with a concentration of 5 to 6 times will be obtained. Came. Then, during arthroscopic surgery, it is injected in the shoulder at the site of injury. In the other group, PRP injection is not performed during arthroscopic surgery. This study is conducted in the orthopedic department of Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

inclusion criteria : age between 18 and 70 years old symptoms of rotator cuff tears MRI findings of minor to medium rotator cuff tears exclusion criteria: a history of shoulder surgery, achronic dislocation pregnant or lactating women rheumatoid arthritis gout blood diseases severe cardiovascular dis-eases infections immunodepression patients receiving anticoagulant therapy

Intervention groups

In the intervention group, PRP injection is performed after obtaining 20 cc of blood during arthroscopic surgery.

Main outcome variables

range of motion and strength of internal and external rotation of the shoulder, pain, ultrasound findings

General information

Reason for update

Acronym

PRP

IRCT registration information

IRCT registration number: **IRCT20220803055610N2**
Registration date: **2023-05-31, 1402/03/10**
Registration timing: **prospective**

Last update: **2023-05-31, 1402/03/10**
Update count: **0**

Registration date

2023-05-31, 1402/03/10

Registrant information

Name

Nima Bagheri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6658 1690

Email address

mahdieh.ghiasi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-09-22, 1402/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the Role of Platelet-Rich Plasma in Shoulder Rotator Cuff Repair With Arthroscopy

Public title

Investigating the Effect of Platelet-Rich Plasma in Arthroscopy

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

age between 18 and 70 years old symptoms of rotator cuff tears MRI findings of minor to medium rotator cuff tears

Exclusion criteria:

a history of shoulder surgery, achronic dislocation or pyogenic infection, or rotator cuffarthropathy with glenohumeral osteoarthritis a large ormassive tear (anteroposterior size > 30 mm) during surgery pregnant or lactating women rheumatoid arthritis gout blood diseases severe cardiovascular dis-eases infections immunodepression patients receiving anticoagulant therapy patients with haemoglobin values < 11 g/dl and platelet values < 150, 000/mm 3.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients referred to the orthopedic department with the diagnosis of rotator cuff tendon injuries, which are small and medium tears, are selected by an orthopedic specialist by MRI examination and examinations based on the VAS index and shoulder function. Then the relevant questionnaires are completed. Patients are divided into two groups according to the table of random numbers, the first group is injected with PRP during arthroscopic surgery and the second group is performed alone. In two groups, after 3 and 8 weeks and 3 and 6 months, the patients are examined by performing examinations and completing the questionnaire again.

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 Tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran,Tehran Medical sciences,Tehran

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2023-05-08, 1402/02/18

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.037

Health conditions studied

1

Description of health condition studied

Small and medium rotator cuff tears of the shoulder

ICD-10 code

M65-M68

ICD-10 code description

Small and medium rotator cuff tears of the shoulder

Primary outcomes

1

Description

Pain

Timepoint

Every 2 weeks to eight weeks

Method of measurement

VAS score

2

Description

Range of motion

Timepoint

Every two weeks to three months

Method of measurement

Goniometer

3

Description

Ultrasound Findings

Timepoint

At the beginning of the study and after 3 months

Method of measurement

Ultrasound probe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After confirming the diagnosis and referring to the orthopedic department, the patients are randomly divided into two groups. For one group, PRP injection was performed, in which the prepared prp is injected in the shoulder area during arthroscopic surgery, and the changes created during 6 months after the end of the injection are measured. In this group, 20 cc of venous blood is taken and the blood sample is separated from the platelet-rich plasma by the Selex centrifuge under the RCF protocol. After 8 weeks, all investigations, including the amount of pain, function, and ultrasound changes, are repeated and a comparison is made between the clinical and paraclinical symptoms of the patient before and after the intervention.

Category

Treatment - Drugs

2

Description

Control group: In the control group, only arthroscopic surgery is performed and PRP is not injected.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Orthopedics, Imam Khomeini Hospital,

Full name of responsible person

Nima Bagheri

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Department of orthopedic, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

The research assistant of Tehran University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nima Bagheri

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Data will be shared after de-identifying individuals on pain, range of motion, shoulder function, and tendon thickness.
When the data will become available and for how long
12 months after the results are published
To whom data/document is available
For researchers and workers in academic centers
Under which criteria data/document could be used
For use in research or essays
From where data/document is obtainable
by e-mail or mobile and request on the research gate website
What processes are involved for a request to access data/document
It will be sent to the applicant by email 3 months after the request
Comments