Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of platelet-rich plasma in the treatment of shoulder tendonitis

Protocol summary

Study aim

۱- Evaluation of the comparative effect of platelet-rich plasma and corticosteroid injections in tendonitis patients ۲- Investigating the effect of platelet-rich plasma in relieving tendon inflammation ۳- Assessment the effect of platelet-rich plasma in reducing pain

Design

Two study groups have been designed. that patients are randomly divided into two groups. 100 patients are selected in each group. This clinical trial study has a control group, with parallel, double-blind and randomized groups. Processing of platelets and how to select patients to enter the study have been considered in this project.

Settings and conduct

This project is carried out in the Orthopedic Department of Imam Hospital and the Research Center and Transplant Products Bank. The injection patients are selected by the doctor and samples are prepared in the research center. To prepare PRP, 20 cc of blood is taken from patients. At first, the questionnaire is completed by the patients. The consent form is also completed by the patients

Participants/Inclusion and exclusion criteria

A shoulder injury that has lasted more than 3 months, the range of motion of their shoulder joint is limited, the absence of radicular pain, the absence of inflammatory disorders such as rheumatoid, and the absence of a complete rotator cuff tear, and the absence of corticosteroid injections in the past three months. The patient's unwillingness to continue treatment and perform shoulder joint surgery and the occurrence of other joint disorders

Intervention groups

There are two groups including PRP injection and coronet injection group. Cortone group is the control group. In this study, the effect of PRP compared to corticosteroids is investigated.

Main outcome variables

Shoulder internal and external rotation range of motion, Shoulder internal and external rotation strength, the pain, Ultrasound findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220803055610N1**
Registration date: **2022-12-22, 1401/10/01**
Registration timing: **prospective**

Last update: **2022-12-22, 1401/10/01**
Update count: **0**

Registration date

2022-12-22, 1401/10/01

Registrant information

Name
Nima Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6658 1690

Email address
mahdieh.ghiasi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-19, 1401/10/29

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of platelet-rich plasma in the treatment of shoulder tendonitis

Public title

PRP in tendonitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain is the most common symptom. Physical examination findings include pain on movement, weakness and positive tests Diagnosis of rotator cuff tendinopathy with musculoskeletal ultrasound Symptoms have been persistent for more than 3 months and conservative treatment has failed for at least 4 weeks of formal medical treatment and physical therapy.

Exclusion criteria:

Full-thickness rotator cuff tear Current treatment with anticoagulation Steroid injection in the past 6 months in the injuredshoulder Prior PRP treatment to the injured shoulder Bleeding disorders or preoperative platelet countless than 50,000 Presence of another disease that may causeshoulder pain and dysfunction as rheumatoidarthritis Prior surgery to the injured shoulder

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

The simple random allocation method is that from the beginning, the intervention group (platelet-rich plasma) will be given odd numbers and the control group (Corton) will be given even numbers. Then, according to the number of the studied sample, the corresponding numbers are extracted using the computer, 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. An envelope is given in order of numbers. In order to maintain randomization, the person who prepares the envelopes is different from the person who registers the patients and provides the envelopes to the patients. Registration of patients and their allocation in each of the groups is done by someone other than the doctor.

Blinding (investigator's opinion)

Single blinded

Blinding description

For one group, PRP injection was performed, and in this method, the patient had one PRP injection. In this group, 20 cc of venous blood was takenIn this case, 3 cc of liquid containing platelets with 5 to 6 times concentration will be obtained.The samples will be sent to the laboratory before and after centrifugation to prove platelet concentration. Then, with another syringe, the remaining 3 cc is injected under ultrasound guidance at the tendon tear site. In the other group, corten injection is done intra-articularly. In order to blind the patients, a blood sample is taken from this group before the injection, and in order to maintain medical ethics, the blood sample is sent to the laboratory to count the blood cells. Also, when injecting, adhesive tape is used around the syringe so that the patient does not notice the injected substance.

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,

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

Approval date

2022-10-30, 1401/08/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.183

Health conditions studied

1

Description of health condition studied

shoulder tendonitis

ICD-10 code

M75.1

ICD-10 code description

Rotator cuff tear or rupture, not specified as traumatic

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
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, and in this method, the patient was injected with PRP once every one month, and the changes made during this period were measured up to one year after the end of the injection. In people of this group, 20 cc of venous blood is taken and by Selex centrifuge machine under RCF protocol, the blood sample is separated from platelet-rich plasma in patients and injected by sono guide.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
The second group receives corticosteroid injection in the form of methylprednisolone 40 mg once according to the diagnosis of the orthopedic specialist. 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

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Orthopedics, Imam Khomeini Hospital,
Full name of responsible person
Nima Bagheri
Street address
Department of orthopedic, Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1690
Email
mahdieh.ghiasi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotuhi
Street address
Keshavarz Blvd., Qods Corner, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 81631
Email
mahdieh.ghiasi@yahoo.com
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
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1690
Email
mahdieh.ghiasi@yahoo.com

Person responsible for scientific 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
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6658 1690
Email
nimab1360@gmail.com

Person responsible for updating data

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
Street address
Keshavarz Blvd., Qods Corner, Tehran University of Medical Sciences Headquarters
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6658 1690
Email
mahdieh.ghiasi@yahoo.com

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
6 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