

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Comparison of the effect of ultrasound guided intra-articular injection of corticosteroids and platelet-riched plasma in the treatment of rotator cuff tendinopathy

Protocol summary

Study aim

Comparison of the effect of ultrasound guided intra-articular injection of corticosteroids and platelet-riched plasma in the treatment of rotator cuff tendinopathy

Design

A double-blind clinical trial on 60 patients, simple randomization using the random numbers table, phase 3, with two parallel case and control groups.

Settings and conduct

In this double-blind clinical trial study, all patients diagnosed with tendinopathy without complete tendon rupture who refer to Shahid Beheshti Hospital are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: shoulder pain for more than three months, tendinopathy and partial tear of rotator cuff tendons, MRI findings of tendinopathy or incomplete rotator cuff tear and exclusion criteria: complete tear of cuff tendons, history of shoulder surgery in 6 In the last month, the presence of rheumatological inflammatory diseases, the presence of shoulder instability based on examinations, the history of corticosteroid injection in the shoulder joint during the past 3 months, the history of PRP treatment in the past 6 months, the lack of patient satisfaction.

Intervention groups

In the first group of PRP injections, by taking 35 cc of venous blood with 5 cc of EDTA, it was divided equally into 4 tubes, and the first round was performed for 10 minutes at a speed of 1600 rpm, and then the plasma It enters two pipes and the second round is done at a speed of 3500 rpm for 6 minutes. In this case, 6 cc of liquid containing platelets with a concentration of 5 to 6 times is obtained, which is divided into two syringes in the amount of 3 cc. 3 cc of it is injected intra-articularly at an angle of 30-45 degrees from posterolateral. The second group receives corticosteroid injection in the form

of methylprednisolone 40 mg intra-articularly.

Main outcome variables

Shoulder pain and range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221029056333N3**

Registration date: **2023-04-28, 1402/02/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-28, 1402/02/08**

Update count: **0**

Registration date

2023-04-28, 1402/02/08

Registrant information

Name

Mehdi Tavasoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-10, 1402/01/21

Expected recruitment end date

2023-06-11, 1402/03/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ultrasound guided intra-articular injection of corticosteroids and platelet-rich plasma in the treatment of rotator cuff tendinopathy

Public title

Effect of ultrasound guided intra-articular injection of corticosteroids and platelet-rich plasma in the treatment of rotator cuff tendinopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Shoulder pain that lasts more than three months
Tendinopathy and partial rupture of rotator cuff tendons
MRI findings of tendinopathy or incomplete rotator cuff tear

Exclusion criteria:

Complete rupture of rotator cuff tendons
History of shoulder surgery in the last 6 months
Presence of rheumatological inflammatory diseases
Shoulder instability is based on examinations
The history of corticosteroid injection in the shoulder joint in the last 3 months
History of PRP treatment in the last 6 months
Dissatisfaction of patients

Age

From **40 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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People included in the study will be randomized by simple random method. Tables of random numbers found in many statistical reference books will be used to randomize the numbers. Numbers between 0 and 24 are assigned to the first group, numbers between 25 and 49 are assigned to the second group. The study group includes Cortone and PRP. Concealment is done in consecutively numbered, sealed, opaque envelopes and is kept by the department secretary.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial in which the participant, the outcome assessor and the data analyst will be unaware of the treatment process. After randomization, the patients of each treatment group are

introduced by researcher 1 (one of the executive residents) to researcher 2 to evaluate the outcome. Researcher 2 (one of the supervisors) is only an outcome assessor and records the results without knowing the type of treatment and its effects. A person who is an information analyst (statistician) also receives the recorded information at the end of the work and is not in the process of the intervention groups in any way. Patients also do not know about the injectable substance. Blood is taken from all patients. Plasma in two intervention groups is drawn in a covered syringe.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Health Research Institute - Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

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Postal code

4716681451

Approval date

2023-03-12, 1401/12/21

Ethics committee reference number

IR.MUBABOL.HRI.REC.1401.287

Health conditions studied**1****Description of health condition studied**

Rotator cuff tendinopathy

ICD-10 code

M75.1

ICD-10 code description

Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes**1****Description**

Pain

Timepoint

Before treatment and 1, 2, 3, and 6 months after the

start of treatment
Method of measurement
Using the VAS scale & record severe pain intensity

2

Description

Shoulder range of motion

Timepoint

Before treatment and 1, 2, 3, and 6 months after the start of treatment

Method of measurement

By goniometer

Secondary outcomes

1

Description

Patients' performance

Timepoint

Before treatment and 1, 2, 3, and 6 months after the start of treatment

Method of measurement

Disabilities of the Arm, Shoulder and Hand Outcome L₁
DASH

Intervention groups

1

Description

Intervention group: For this group, PRP injection is performed. In this method, the patient had one PRP injection. In this group, 35 cc of venous blood was taken along with 5 cc of EDTA (Ethylenediaminetetra-acetic acid) and divided equally into 4 tubes. And by Royagen centrifuge machine, the first round is done for 10 minutes at a speed of 1600 rpm and then the obtained plasma enters two tubes and the second round will be done at a speed of 3500 rpm for 6 minutes. In this case, 6 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, 6 cc of the obtained liquid is divided into two syringes with 3 cc each. 3 cc of that injection is performed by a resident project manager intra-articularly with an angle of 30-45 degrees from posterolateral.

Category

Treatment - Drugs

2

Description

Control group: This group receives corticosteroid injection in the form of methylprednisolone (depomedrol) 40 mg intra-articularly.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr. Mehdi Tavasoli

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

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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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehrdad Mostafalo

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Radiology

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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**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