

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparative study of corticosteroid injections and platelet rich plasma in the treatment of patients with shoulder tendinopathy compare sonographic findings

#### Protocol summary

##### Study aim

Comparison of clinical findings in patients Shoulder tendinopathy with Platelet Rich Plasma and corticosteroid injecting Comparison of the effect of PRP and corticosteroid on pain relief in patients with shoulder tendonopathy Comparison of the effect of PRP and corticosteroid on the range of motion of patients with shoulder tendonopathies Comparison of PRP effect on and corticosteroid supraspinatus tendon thickness in patients with shoulder tendonopathies Comparison of WORC and DASH questionnaire score changes after PRP and corticosteroid injection in patients with shoulder tendonopathy

##### Design

Randomized clinical trial, single blind, parallel group, 56 patients

##### Settings and conduct

The study (injection and exercise therapy) was performed in the sports medicine department of Rasoul Hospital.

##### Participants/Inclusion and exclusion criteria

Shoulder pain that lasts more than three months (162)  
Age over 40 years

##### Intervention groups

PRP injection group, The other group, corticosteroid injections a

##### Main outcome variables

Pain, Range of Motion, Thickness of tendon

#### General information

##### Reason for update

Increase the follow-up time of patients after shoulder injection

##### Acronym

PRP

##### IRCT registration information

IRCT registration number: **IRCT201302174251N9**

Registration date: **2013-05-03, 1392/02/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-16, 1399/02/27**

Update count: **1**

##### Registration date

2013-05-03, 1392/02/13

##### Registrant information

###### Name

Haleh Dadgostar

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2200 4050

###### Email address

dadgostar.h@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences

##### Expected recruitment start date

2013-04-21, 1392/02/01

##### Expected recruitment end date

2015-04-21, 1394/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative study of corticosteroid injections and

platelet rich plasma in the treatment of patients with shoulder tendinopathy compare sonographic findings

#### Public title

Comparing the effect of corticosteroid injections and platelet rich plasma on the treatment of shoulder tendinopathy

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Shoulder pain that lasts for more than 3 months limited shoulder range of motion Absence of radicular pain Inflammatory disorders such as rheumatoid arthritis Fibromyalgia lack of complete rotator cuff tear The ligament laxity Non-corticosteroid injections in the past three months

##### Exclusion criteria:

Unwillingness of the patient to continue treatment shoulder joint surgery The presence of other disorders that limit joint motion such as frozen shoulder

#### Age

From **40 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

#### Sample size

Target sample size: **56**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Patients are randomly divided into two groups based on random number table after confirming the diagnosis with MRI and referring to the sports medicine department.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The platelet rich plasma group is injected one time. In this group, 35 ml of venous blood was taken and by the Selex centrifuge under the RCF protocol, the blood sample is separated from rich plasma platelet by 1700 and 3200 rpm. Plasma rich platelets are separated after adding calcium gluconate 10% cc platelet concentrate obtained. The injection is performed by a sports medicine specialist in the form of intraarticular with an angle of 30-45 degrees from the posterolateral. And if there is a partial rupture in tendon, 3 cc PRP injection is performed under ultrasound guidance at the tendon rupture site. One week after the injection, the patient is visited, examined, given the necessary advice and also exercise prescription. Exercise is divided to scapula rehabilitation and shoulder muscles training. After one and three months, repeated examinations, including pain, function, Completion of WORC, DASH questionnaire and ultrasound changes was achieved , and a comparison between the patient's clinical and Para

clinical symptoms within these periods was performed. The injection for corticosteroid group, however, is applied Methylprednisolone 40 mg once. For patients, one cc of Depomedrol and one cc of 2% lidocaine solution are injected into the intra articular joint in the same PRP manner. In this group, due to the blindness of the study, blood sampling of the patient is performed before corticosteroid injection.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran University of Medical Sciences

##### Street address

Ghods street Keshavars Blv

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

#### Approval date

2012-07-20, 1391/04/30

#### Ethics committee reference number

19910-91-4-30

## Health conditions studied

### 1

#### Description of health condition studied

Shoulder Tendinopathy

#### ICD-10 code

M75.1

#### ICD-10 code description

rotator cuff syndrome rotator cuff or supraspinatous tear or rupture (complete ) ( incomplete ) not specified as traumatic

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

every 2 weeks up to 8 weeks

#### Method of measurement

VAS scale

## 2

### **Description**

range of motion

### **Timepoint**

every 2 weeks up to 3 months

### **Method of measurement**

Goniometer

## 3

### **Description**

Sonographic finding

### **Timepoint**

at base line and 3 months later

### **Method of measurement**

Sonographic prob

## **Secondary outcomes**

empty

## **Intervention groups**

## 1

### **Description**

The platelet rich plasma group is injected twice within a month. In this group, 20 ml of venous blood was taken by centrifuges Selex protocol RCF, blood samples from the men with the 1800 and 2000 cycles and women with 1600 and 2000 cycle. Plasma rich platelets are separated after adding calcium gluconate 10% cc platelet concentrate obtained. Under ultrasound Guide, in collaboration with a radiologist and a sports medicine specialist in the area of sub-45 degree lateral Acromion is injected (based on Sonographic Guide). Assessment of clinical sing such as pain (based on VAS measurement), shoulder range of motion and its function is occurred. Moreover, musculoskeletal sonography is applied by two clinician experts. These (findings are) recorded and compared

### **Category**

Treatment - Drugs

## 2

### **Description**

The injection for corticosteroid group, however, is applied MethylPrednisolone 40 mg once or twice within a month based on the Rheumatologist decision. At the baseline, after four weeks and also eight weeks after intervention, all the studies including pain, range of motion, function, and Sonographic findings changes are evaluated and compared with the data which is recorded before intervention

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Rasoul Akram Hospital

#### **Full name of responsible person**

Haleh Dadgostar MD

#### **Street address**

Shahr ara street Sattar khan street

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1445613131

#### **Phone**

+98 21 6435 2446

#### **Email**

dadgostar.h@iums.ac.ir

## 2

### **Recruitment center**

#### **Name of recruitment center**

Emam Khomeini hospital

#### **Full name of responsible person**

Shafieh Movaseghi MD

#### **Street address**

End of Keshavars Blv

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1417653761

#### **Phone**

+98 21 6436 2446

#### **Email**

movaseghi@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Abbas Motavalian, MD

#### **Street address**

Hemmat highway, Iran University of Medical Sciences

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۴۴۹۶۱۴۵۳۵

#### **Phone**

+98 21 8670 3020

#### **Email**

hldadgostar@gmail.com

#### **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****Contact****Name of organization / entity**

sports medicine department Rasoul e Akram hospital

**Full name of responsible person**

Haleh Dadgostar MD

**Position**

Associated Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

Shahr Ara street Sattar khan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 2446

**Fax****Email**

hldadgostar@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sports Medicine Research Center Tehran University of Medical Sciences Tehran Iran

**Full name of responsible person**

Haleh Dadgostar MD

**Position**

Assistance Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

Shahr Ara street Sattar khan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 2446

**Fax****Email**

hldadgostar@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Sports Medicine department, Rasoul e Akram Hospital

**Full name of responsible person**

Haleh Ddagostar MD

**Position**

Associated Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

**Street address**

Shahr Ara street sattar khan street

**City**

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 2446

**Fax****Email**

hldadgostar@gmail.com

**Web page address****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**

After deidentifying participants, sharing data related to pain, ROM, function and thickness of tendon will be happened

**When the data will become available and for how**

**long**

starting 6 months after publication

**To whom data/document is available**

Researchers and people working in Academic institution

**Under which criteria data/document could be used**

To applied in research or manuscript

**From where data/document is obtainable**

Personal email, Mobile phone , research gate

**What processes are involved for a request to access data/document**

3 months after applying, the document will send through email

**Comments**