

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the efficacy of platelet-rich plasma with corticosteroid in the Treatment of patients with frozen shoulder

Protocol summary

Study aim

Evaluation of the efficacy of platelet-rich plasma injection compared to corticosteroid injection in patients with frozen shoulder

Design

Clinical trial with control group, with parallel groups, double blind, randomized, phase 3 on 75 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients with frozen shoulder disease referred to the Shafa Yahyaian Hospital will be randomly assigned into the three groups: platelet-rich plasma injection, corticosteroid injection, and normal saline injection. The efficacy of platelet-rich plasma will be compared with that of corticosteroids. The participant, the injector, and the outcome evaluator will not be informed of the treatment offered to the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of frozen shoulder disease by an orthopedic surgeon Age 18 to 80 years Providing Inform consent to participate in the study Exclusion criteria: History of frozen shoulder Other shoulder-related diseases include calcified tendonitis, rotator cuff arthropathy, severe osteoarthritis of the shoulder, or a history of recurrent or late shoulder dislocation History of shoulder surgery Accompanying musculoskeletal patients including severe osteoarthritis, rheumatoid arthritis, fibromyalgia, and etc. Recent development of severe psychiatric disorders such as psychosis, mania, suicide and major cognitive impairment depression such as mental retardation or dementia

Intervention groups

The first intervention group will receive 8 ml of platelet-rich plasma intra-articularly. The second intervention group will receive 2 ml of methylprednisolone acetate (40 mg) combined with 2 ml of 2% lidocaine and 11 ml of normal saline intra-articularly. The control group will receive 13 ml of normal saline combined with 2 ml of 2% lidocaine internally.

Main outcome variables

Shoulder pain, Shoulder function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190903044677N2**

Registration date: **2022-03-25, 1401/01/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-25, 1401/01/05**

Update count: **0**

Registration date

2022-03-25, 1401/01/05

Registrant information

Name

Pouria Tabrizian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2041

Email address

tabrizian.pouria@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-21, 1400/12/02

Expected recruitment end date

2023-02-21, 1401/12/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of platelet-rich plasma with corticosteroid in the Treatment of patients with frozen shoulder

Public title

Evaluation of the effect of platelet-rich plasma in the treatment of frozen shoulder disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of frozen shoulder disease by an orthopedist
Providing informed consent to participate in the study

Exclusion criteria:

History of frozen shoulder
Other shoulder-related diseases include calcified tendonitis, rotator cuff arthropathy, severe osteoarthritis of the shoulder, or a history of recurrent or late shoulder dislocation
History of shoulder surgery
Accompanying musculoskeletal patients including severe osteoarthritis, rheumatoid arthritis, fibromyalgia, etc.
Recent development of severe psychiatric disorders such as psychosis, mania, suicide and major cognitive impairment
depression such as mental retardation or dementia

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with Excel RAND function will be implemented. To create a random chain of 3 groups of 25, in a column, 25 letters A, 25 letters B, and 25 letters C, and in the adjacent column, 75 random numbers are made by order of RAND. The composition of both columns is arranged based on the random numbers from large to small. The sequence of letters A, B, and C is used. These numbers are placed in opaque envelopes, and one envelope is assigned to each patient. Finally, the envelope is opened and the assigned treatment group is identified.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participating patients and injectors will be blind to the type of treatment used for each patient. To blind patients, they will be told that they will receive one of three treatments: corticosteroids, platelet-rich plasma, or

normal saline. To blind the injector, the solution is first drawn into a syringe in another room by a trained nurse and covered with a label on the syringes so that the difference of liquid inside is not clear. The ready for injection syringe is then handed to the doctor for injection.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad Tower, Hemat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2020-12-13, 1399/09/23

Ethics committee reference number

IR.IUMS.REC.1399.996

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

Frozen Shoulder

ICD-10 code

M75.0

ICD-10 code description

Periarthritis of shoulder

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

Shoulder pain

Timepoint

Before the start of intervention and weeks 3, 6 and 12 after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Shoulder function

Timepoint

Before the intervention and weeks 3, 6 and 12 after the intervention

Method of measurement

Disabilities of the arm, shoulder and hand Questionnaire

Intervention groups

1

Description

First intervention group (injection of platelet-rich plasma): 20 ml of blood will be taken from patients and poured into two tubes for separation of platelet-rich plasma (Noavaran Salamat Arjang Co. with a volume of 10 cc). Then, it will be centrifuged at 1800 rpm for 14 minutes. 4 ml of platelet-rich plasma is extracted from each tube and a total of 8 ml of platelet-rich plasma is injected intra-articularly to the patient's shoulder within a maximum of half an hour after blood sampling.

Category

Treatment - Drugs

2

Description

Second intervention group (corticosteroid injection group): 2 ml of methylprednisolone acetate (40 mg) is combined with 2 ml of 2% lidocaine and 11 ml of normal saline and the resulting solution will be injected intra-articularly into the patient's shoulder.

Category

Treatment - Drugs

3

Description

Control group: 13 ml of normal saline in combination with 2 cc of 2% lidocaine will be injected intra-articularly into the patient's shoulder.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaieian Hospital

Full name of responsible person

Pouria Tabrizian

Street address

Shafa Yahyaieian Hospital, In front of gas station, Mojahedine-Islam Ave, Shohada Sq

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Email

tabrizian.pouria@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranshahr University of Medical Sciences

Full name of responsible person

Mahmoudreza Mohaghegh

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Phone

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Email

admins@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranshahr 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

Iranshahr University of Medical Sciences

Full name of responsible person

Pouria Tabrizian

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

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

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Position

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Latest degree

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Title and more details about the data/document

All data is potentially shareable after unidentified individuals

When the data will become available and for how long

Start of access period from 1402

To whom data/document is available

The data of this study will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

The data will be available if the request is sent to the email of the project manager, and any kind of analysis of the data is allowed.

From where data/document is obtainable

To receive the data, Dr. Pouria Tabrizian should be contacted through the following ways: Postal Address: ddressShafa Yahyaeian Hospital, In front of the gas station, Mojahedine-Islam Ave, Shohada Sq P.O BOX:1157637131 Telephone: 0098 21 33542041 Fax: 0098 21 33542020 Mobile: 0098 9155216214 Email: tabrizian.pouria@gmail.com

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

After sending an email to request the documents and reviewing the request by the project executor, the applicant will refer to the introduced center with the identification documents on the specified date and receive the documents.

Comments