

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

A COMPARISON OF THE CLINICAL OUTCOMES OF PRP INJECTION AND ARTHROSCOPIC RELEASE FOR THE TREATMENT OF FROZEN SHOULDER BASED ON CLINICAL TESTS

Protocol summary

Study aim

COMPARISON OF THE CLINICAL OUTCOMES OF PRP INJECTION AND ARTHROSCOPIC RELEASE FOR THE TREATMENT OF FROZEN SHOULDER BASED ON CLINICAL TESTS

Design

This prospective, interventional study will be performed on clinical trials. 126 patients with frozen shoulder who referred to the orthopedic clinic in 1398 will enrolled in an easy non-probable way. Patients will be randomly allocated into three groups of 42 people. The first person will treated with PRP followed by physiotherapy and the second one will treated by arthroscopy followed by physiotherapy and the third one was physiotherapy alone, and this trend continued until 42 subjects Arrived Finally.

Settings and conduct

Patients' demographic information including their age, gender, BMI, and diabetes, be recorded in a checklist. The first group of subjects received PRP treatment followed by physiotherapy, PRP group will received 2 cc PRP in shoulder. the second group will be treated with arthroscopic release followed by physiotherapy and the third one or controlled group will received only physiotherapy. In the end, patients were examined in the next 6 weeks, 6 months and 12 months.

Participants/Inclusion and exclusion criteria

inclusion criteria: all the patient with frozen shoulder.
exclusion criteria:less than 30 years old,more than 70 years old,patient who had any operation in same shoulder to treat frozen shoulder,any fracture around the shoulder, shoulder joint septic arthritis.

Intervention groups

Patients will be randomly allocated into three groups of 42 people. The first group will treated with PRP, and the second one will treated by arthroscopy, and the third one or control group was physiotherapy alone.

Main outcome variables

1. patient score in AMERICAN SHOULDER AND ELBOW QUESTIONARY
2. patient score in SIMPLE SHOULDER TEST
3. patient score in Oxford shoulder score final.

General information

Reason for update

Acronym

PRP in FS

IRCT registration information

IRCT registration number: **IRCT20190618043932N1**

Registration date: **2019-07-25, 1398/05/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-25, 1398/05/03**

Update count: **0**

Registration date

2019-07-25, 1398/05/03

Registrant information

Name

amir reza sadeghifar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3222 8000

Email address

a.sadeghifar@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-21, 1398/03/31

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A COMPARISON OF THE CLINICAL OUTCOMES OF PRP INJECTION AND ARTHROSCOPIC RELEASE FOR THE TREATMENT OF FROZEN SHOULDER BASED ON CLINICAL TESTS

Public title

PRP in frozen shoulder

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All of the patient with frozen shoulder that refer to orthopedic clinic for treatment. Patient must be have 30 to 70 years old

Exclusion criteria:

less than 30 years old More than 70 years old Patient who had any operation in same shoulder to treat frozen shoulder. Any fracture aroun the shoulder (acromion,clavicle,coracoied,scapulla) Shoulder joint septic arteritis.

AgeFrom **18 years** old to **70 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **126****Randomization (investigator's opinion)**

Randomized

Randomization description

126 patient with frozen shoulder that refer to orthopedic clinic in 1398 will enrolled in an easy non-probable way. Patients were randomly allocated into three groups of 42 people. The first person was treated with PRP followed by physiotherapy and the second one was treated by arthroscopy followed by physiotherapy and the third one was physiotherapy alone, and this trend continued until 42 subjects Arrived Finally

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Factorial

Other design features

No spesefic design.

Secondary Ids

empty

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

Ethics committee of kerman University of Medical Sciences

Street address

Qarani ave, shariati ave, bahonar hospital, kerman

City

kerman

Province

Kerman

Postal code

7613747181

Approval date

2019-02-22, 1397/12/03

Ethics committee reference number

IR.kmu.rec.1397.485

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

frozen shoulder

ICD-10 code

M75.00

ICD-10 code description

Adhesive capsulitis of unspecified shoulder

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

1. patient score in AMERICAN SHOULDER AND ELBOW QUESTIONARY 2. patient score in SIMPLE SHOULDER TEST 3. patient score in Oxford shoulder score final.

Timepoint

patients will be followed preintervention, in the next 6 weeks, 6 months and 12 months.

Method of measurement

1. AMERICAN SHOULDER AND ELBOW QUESTIONARY 2. SIMPLE SHOULDER TEST 3. OXFORD SHOULDER SCORE FINAL.

Secondary outcomes

empty

Intervention groups**1****Description**

intervention group: PRP group: all the patients will be fill questioneries preintervention. then will be received 2 cc PRP in posterior portal of shoulder arthroscopy. patient receive physiotherapy after injection. patient will be followed by questioneries after 6weeks, 6months and

12 months later.
Category
Treatment - Drugs

2

Description
Intervention group: arthroscopic release group: all the patients will be fill questioneries preintervention. then will be under shoulder arthroscopy under general anesthesia. then patient receive physiotherapy after surgery. patient will be fallowed by questionarys after 6weeks, 6months and 12 months later.

Category
Treatment - Surgery

3

Description
Control group: physiotherapic group. all the patients will be fill questioneries preintervention. then patients receive physiotherapy. patient will be fallowed by questioneries after 6weeks, 6months and 12 months later.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Besate 2, orthopedic clinic
Full name of responsible person
DR khalilkargar shooroki
Street address
Besate2 clinic, Qrani ave, shariati Ave
City
kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3223 5011
Email
a.sadeghifar@kmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
amirreza sadeghifar
Street address
kerman univercity of medical since,mostafa khomeini Ave, emam khomeyni highway, kerman
City

kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
sit@kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Dr amirreza sadeghifar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Qarani Ave, bahonar hospital
City
kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3132 5700
Email
a.sadeghifar@kmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr amirreza sadeghifar

Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Besate2 clinic, Qrani ave, shariati Ave
City
kerman
Province
Kerman
Postal code
7613747181
Phone
+98 34 3132 5700
Email
A.sadeghifar@kmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
dr amirreza sadeghifar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
bahonar hospital, Qrani ave, shariati Ave
City
kerman
Province
Kerman
Postal code

7613747181
Phone
+98 34 3132 5700
Email
a.sadeghifar@kmu.ac.ir

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
all data can be available for all the people who interest in PRP.
When the data will become available and for how long
when the research finished.
To whom data/document is available
all data can be available for all the people who interest in PRP.
Under which criteria data/document could be used
for PRP development
From where data/document is obtainable
dr amirreza sadeghifar. a.sadeghifar.kmu.ac.ir
What processes are involved for a request to access data/document
with one call and email address
Comments