# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Comparison the efficacy and durability of treatment effect of autologe PRP with low weight hyaluronic acid on knee osteoarthritis

## Protocol summary

**Summary**

Osteoarthritis is one of the most common joint disorders that is related by aging. It could decrease the quality of life. Most of the current treatments are palliative only and has no effect on the disease process. The goal of this study is to compare the efficacy and durability of treatment effect of autologe PRP with low weight hyaluronic acid on knee osteoarthritis. 76 patients, 49 in PRP group and 27 in Hyaloronic acid group will be follow in 2 and 6 months after injection using VAS and WOMAC index.

## General information

**Acronym**

PRP: Plasma Rich Platelet

**IRCT registration information**

IRCT registration number: **IRCT2015041121697N1**
Registration date: **2015-07-14, 1394/04/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-07-14, 1394/04/23

**Registrant information**

**Name**

Mohammad-Reza Sohrabi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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+98 21 2243 9936

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vice-chancellor for research, School of Medicine, Shahid Beheshti University of Medical Sciences

**Expected recruitment start date**

2013-09-23, 1392/07/01

**Expected recruitment end date**

2014-09-23, 1393/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the efficacy and durability of treatment effect of autologe PRP with low weight hyaluronic acid on knee osteoarthritis

**Public title**

Effect of autologe PRP with hyaluronic acid on knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Chronic pain or swelling for at leas 4 months before radiological findings; degenerative changes in radiology Exclusion criteria: Systemic disorders like diabetes, rheumatoid arthritis; varus or valgus in spine more than 5 degree; hematologic disorders; chronic heart diseases; infections; immune compromise; hemoglobin less than 11; platelet less than 150000; incomplete questionnaire; incomplete treatment course; no interest to participate; multi-arthritis; intra-articular injection of hyaloronic acid in last 6 months; intra-articular injection of steroid in last 3 months

**Age**

No age limit

**Gender**

Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **76**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
We allocate participants to two intervention groups by block random assignment. each block had 2 samples. We followed them for 6 months after intervention.

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics committee of Shahid Beheshti University of Medical Sciences
**Street address**
Parvaneh St., Velenjak.
**City**
Tehran
**Postal code**
**Approval date**
2013-02-24, 1391/12/06
**Ethics committee reference number**
131

## Health conditions studied

**1**

**Description of health condition studied**
Knee osteoarthritis
**ICD-10 code**
M17.0
**ICD-10 code description**
Primary gonarthrosis, bilateral

## Primary outcomes

**1**

**Description**
Knee pain
**Timepoint**
0, 2 and 6 monts after injection
**Method of measurement**
WOMAC questionnaire

**2**

**Description**
Knee pain
**Timepoint**
0, 2 and 6 monts after injection
**Method of measurement**
VAS questionnaire

**3**

**Description**
Knee stiffnes
**Timepoint**
0, 2 and 6 monts after injection
**Method of measurement**
WOMAC questionnaire

**4**

**Description**
Knee function
**Timepoint**
0, 2 and 6 monts after injection
**Method of measurement**
WOMAC questionnaire

## Secondary outcomes

**1**

**Description**
Septic arthritis
**Timepoint**
2 weeks after injection
**Method of measurement**
Inspection

## Intervention groups

**1**

**Description**
Intervention group1: Plasma rich platelet (PRP) done for only one knee, the worth on., Three injection by two weeks interval will be done. PRP is prepared by Blood transfusion organization kits. 10 patients were used to standardization of the Kit in two phases: first 15 Min with 1200/min and second 5 Min with 4000/min in room temperature.
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group2: we use hyaloronic acid (trade mark: Hialgan, made in Germany) in this group. Three injection will be done by 1 week interval.

**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Loghman Hakim Hospital
**Full name of responsible person**
Dr. Zahra HajiHashemi
**Street address**
Makhsus St. Lashkar Cross
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice-chancellor for research, School of Medicine, Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Dr. Ali Ziaie
**Street address**
Parvaneh st., Velenjak
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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**
Vice-chancellor for research, School of Medicine, Shahid Beheshti University of Medical Sciences
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Zahra Hajihashemi
**Position**
Rheumatologist
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
*empty*
**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*