

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison the efficacy and durability of treatment effect of autologous 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 autologous PRP with low weight hyaluronic acid on knee osteoarthritis. 76 patients, 49 in PRP group and 27 in Hyaluronic 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)

Phone

+98 21 2243 9936

Email address

m.sohrabi@sbm.ac.ir

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 autologous PRP with low weight hyaluronic acid on knee osteoarthritis

Public title

Effect of autologous PRP with hyaluronic acid on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Chronic pain or swelling for at least 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 hyaluronic 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

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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

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice-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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Full name of responsible person

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Assistant professor

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Web page address**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