Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effect of the Platelet-Rich Plasma (PRP) injection in primary manifestations of knee osteoarthritis in patients who refer to rheumatology clinic of Kowsar hospital, Semnan

Protocol summary

Summary

Purpose: Assessment the intra-articular injection effect of platelet-rich plasma (PRP) on symptoms of primary osteoarthritis. Study design: This study is a randomized, double-blind, placebo controlled, uni- center, 2-3 phase of clinical trials. Study population: patients with primary osteoarthritis of the knee who will refer to Kowsar hospital that are randomly selected. Main inclusion criteria: age 40-60 years, history of chronic knee pain for at least 12 months and a Kellgren-Lawrence radiological criterion. Main exclusion criteria: thrombocytopenia, antiplatelet drugs, corticosteroids, liver or kidney systemic disease, leukemia and lymphoma, congestive heart failure, myocardial infarction and arrhythmias, septic arthritis, intra-articular injection of steroids or hyaluronic acid during the last 6 months, smoking . Sample Size: 60 patients, 30 in the intervention group and 30 patients as control group Interventions: The intervention group patients received autologous PRP injections 3 CC in both knee and patients in control group received placebo injections (empty syring). Time of interventions: The patients will be assessed at initiation, 3 and 6 months after the intervention, using the IKDC, EQ VAS and Tegner criteria. Primary outcome: improving of IKDC, EQ-VAS and Tegner criteria in 3 and 6 months after injection of PRP in compare to before injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010112823N2**
Registration date: **2015-01-19, 1393/10/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-19, 1393/10/29

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the Platelet-Rich Plasma (PRP) injection in primary manifestations of knee osteoarthritis in patients who refer to rheumatology clinic of Kowsar hospital, Semnan

Public title

Effect of the Platelet-Rich Plasma(PRP) injection in

primary manifestations of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- age 40-60 years, 2- a history of chronic knee pain for at least 12 months, 3-Kellgren-Lawrence radiological criteria for having developing osteoarthritis of the knee (grade 1 and 2). Exclusion criteria: 1. Thrombocytopenia, 2- taking anticoagulant agents during the past 2 weeks 3- taking immunosuppressive drugs, NSAIDs and corticosteroids, 4- liver or renal disease, 5- leukemia and lymphoma, 6- a history of malignancy, active malignant disease, 7- severe cardiovascular disease including congestive heart failure, myocardial infarction and cardiac arrhythmia, 8- bacterial arthritis at least during last 6 months, 9- intra-articular injection of steroid or hyaluronic acid during the last 6 months, 10- use of cigarettes and tobacco 11- fever and systemic infections and local infection in injection site.

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee, Semnan university of Medical Sciences

Street address

Basidj Boulevard

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Semnan

Postal code

3519899951

Approval date

2015-01-13, 1393/10/23

Ethics committee reference number

93/551664

Health conditions studied

1

Description of health condition studied

primary manifestations of osteoarthritis

ICD-10 code

Gonarthros

ICD-10 code description

M17

Primary outcomes

1

Description

Pain

Timepoint

Befor and 3 and 6 months after intervention

Method of measurement

IKDC, EQ-VAS and Tegner criteria

Secondary outcomes

1

Description

Physical Activities

Timepoint

6 months after intervantion

Method of measurement

IKDC، EQ-VAS and Tegner criteria

Intervention groups

1

Description

In the first group (N=30) 3 CC autologous PRP by a syringe which covered in aluminum foil will be intraarticularly injected. The patient is not aware of the contents of the syringe (real injections).

Category

Treatment - Drugs

2

Description

For patients in the control group (n=30) an empty syringe which covered by aluminum foil prepared and its needle enter up to 5 mm into skin and fat tissue without entering into the joint space (Pseudo injection).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Kowsar Hospital

Full name of responsible person
Dr. Jamileh Moghimi

Street address
Amin Ave., Alghadir square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research and Technology, Semnan University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Asgari

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Basidj Boulevard

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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 and Technology, Semnan 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
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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