

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Platelet-rich plasma injection plus oral celecoxib vs saline injection plus oral celecoxib to treat knee osteoarthritis:a randomized single-blind clinical trial.

Protocol summary

Summary

Aim: Evaluation of efficacy of Platelet-rich plasma injection to treat knee osteoarthritis. Design: A single-blinded, Placebo controlled, single center, randomized clinical trial Studied population: patients with the age between 40-65 with chronic pain more than 6 months whom are suffered from knee osteoarthritis (Kellgren Lawrence score 2 or 3) Sample size: 60 cases Intervention: -In intervention group: injection of Plasma-rich Platelet (5 cc) in suffered knee plus administration of oral celecoxib 100 mg two times a day for 3 weeks -In control group: injection of Saline (5 cc) in suffered knee plus administration of oral celecoxib 100 mg two times a day for 3 weeks Outcomes: patients will be assessed pre-treatment, 1 week, 3 and 6 month post treatment follow up visits with regards to pain intensity using VAS (visual Analogue Scale) and functional score using Knee Injury and Osteoarthritis Outcome Score (KOOS).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301167274N6**
Registration date: **2013-02-16, 1391/11/28**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-16, 1391/11/28

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Science

Expected recruitment start date

2012-06-04, 1391/03/15

Expected recruitment end date

2012-09-05, 1391/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Platelet-rich plasma injection plus oral celecoxib vs saline injection plus oral celecoxib to treat knee osteoarthritis:a randomized single-blind clinical trial.

Public title

Evaluation of efficacy of Platelet-rich plasma injection plus oral celecoxib to treat knee osteoarthritis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age between 40-65 years old, patients with a history of chronic (for at least 6 months) knee pain and imaging findings of degenerative changes of the joint (Kellgren Lawrence II or III at X-ray evaluation), no intra-articular injection in the last 3 months, no history of

previous knee trauma or surgery. Exclusion criteria: irregular follow-up visits, taking other NSAIDs during the trial, systemic disorders such as diabetes, rheumatoid arthritis, hematological diseases (coagulopathy), severe cardiovascular diseases, infections, pregnancy, secondary osteoarthritis, patients in therapy with anticoagulants or anti-aggregants, use of NSAIDs in the last week before blood donation and patients with Hb values lower than 11 g/dl and platelet values lower than 150,000/mm³.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee, Guilan University of Medical Sciences

Street address

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue

City

Rasht

Postal code**Approval date**

2012-05-23, 1391/03/03

Ethics committee reference number

1910095603

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

Degenerative Joint Disease

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

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

Pain intensity

Timepoint

Baseline assessment, 1 week and 3 month and 6 month post treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Functional outcome and quality of life

Timepoint

Baseline assessment, 1 week and 3 month and 6 month post treatment

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS)

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

Intervention Group: Single injection of Platelet-Rich Plasma (5 cc) plus administration of oral celecoxib 100 mg two times a day for 3 weeks

Category

Treatment - Drugs

2**Description**

Control group: Injection of Saline plus administration of celecoxib 100 mg two times a day for 3 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam-Reza Clinic of Poursina Hospital

Full name of responsible person

Mohsen Mardani Kivi MD.

Street address

Imam-Reza clinic, Poursina hospital, Parastar avenue

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Science

Full name of responsible person

Prof. Abdolrasoul Sobhani, Research chancellor of Guilan university of medical science

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 source

Vice chancellor for research, Guilan University of Medical Science

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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Assistant Professor

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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