Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 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

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Guilan University of Medical Sciences
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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/mm 3.

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
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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

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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