

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

A double blinded clinical trial for evaluation of PRP(Platelet riched plasma) with prolotherapy intraarticular injection on pain score and range of motion in knee osteoarthritis

Protocol summary

Summary

Objectives: Osteoarthritis is one of the most common disease in human beings and its occurrence in knee increases by age. For the treatment of this disease multiple modalities have proposed and one of them is intra-articular injection of platelet rich plasma (PRP) which is an autologous concentrate from growth factors which causes tissue regeneration. Prolotherapy with dextrose is another treatment for osteoarthritis. Physiologically speaking with increasing in age and after metabolic, biomechanics and trauma the joints will have degenerative changes. Different drugs such as corticosteroids, growth factors, hyaluronic acid, stem cells and ...have been used in order to regenerate the tissue and increase perfusion. The aim of this study is evaluation of a new modality in treatment of osteochondral degenerative disease. Design and Participants including major eligibility criteria and setting and conduct: The sample size is 40 patients. The included osteoarthritic patients will randomly ordered by block randomization in two group and the study will be double blinded which means that patients, research evaluators and study analyzer are not aware of treatment. Intervention: While performing the PRP method 15-200 cc blood (depending on site, number of injection and the used kit)will be centrifuged and in first stage platelets will be extracted from erythrocytes and in second stage platelets will be more purified. Then under strill condition the sample will be injected intra-articularly. In the second group under strele condition dextrose will be injected intra-articularly. Main outcomes: The knee range of motion and pain score and number of pain killer usage will be measured and recorded before performing the injection. The patients will be visited and these factors will be measured in weeks 1, 4 and 8 after injection and recorded for analysis and comparing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101810599N2**

Registration date: **2015-06-27, 1394/04/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-27, 1394/04/06

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran university of medical science Vice chancellor for research

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double blinded clinical trial for evaluation of PRP(Platelet riched plasma) with prolotherapy intraarticular injection on pain score and range of motion in knee osteoarthritis

Public title

Effects of regenerative agents injection in knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Knee osteoarthritis stage I-III according to American Rheumatologist society criteria or radiologic criteria I-III according to Kalgreen-Lawrence criteria, 40-70 years age. Exclusion criteria: addiction to opioids or alcohol, history of rheumatoid arthritis or any rheumatologic disease, hemophilia

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Expressway corner

City

Tehran

Postal code**Approval date**

2014-06-28, 1393/04/07

Ethics committee reference number

92-1-30-17651-101652

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

knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Primary unilateral knee arthrosis

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

Pain score

Timepoint

Before performing the intervention (0) and 1, 4 & 8 weeks after performing the intervention

Method of measurement

Visual analogue scale with specialized ruler and recording in questionnaire

2**Description**

Knee range of motion

Timepoint

Before performing the intervention (0) and 1, 4 & 8 weeks after performing the intervention

Method of measurement

Using goniometer and recording in questionnaire

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

pain killer number

Timepoint

Before performing the intervention (0) and 1, 4 & 8 weeks after performing the intervention

Method of measurement

number of pain killer usage and record in questionnaire

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

In intervention group platelet riched plasma will be injected intra-articular to the knee one time. For preparing this product Biojel kit (USA) will be used which gives 7-10 CC plasma after two stages of centrifugation. In fact growth factors will be extracted from blood for autologus cellular therapy.

Category

Treatment - Surgery

2

Description

In control group dextrose will be injected intra-articular to the knee one time. 7 cc dextrose with concentration of 25%(Ghazi co, Iran) will be used for this purpose.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences-Vice chancellor for research-Hazrat Rasul medical complex- Inter

Full name of responsible person

Poupak Rahimzadeh

Street address

Anesthesiology and pain department

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research- Iran University of Medical Sciences-

Full name of responsible person

Dr Mohammad Musavi- Responsible officer:Ms Azvan

Street address

Hemmat expressway corner

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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- Iran 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

Iran University of Medical Sciences

Full name of responsible person

Poupak Rahimzadeh

Position

Associate professor

Other areas of specialty/work

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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