

# 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)

##### Phone

+98 21 6650 9059

##### Email address

p-rahimzadeh@tums.ac.ir

##### 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

##### City

Tehran

#### 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

#### Street address

Hazrat Rasul Medical complex, Sattar Khan Ave.

#### City

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#### Fax

#### Email

poupak\_rah@hotmail.com; p-rahimzadeh@tums.ac.ir

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## Person responsible for scientific inquiries

### Contact

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#### Full name of responsible person

Poupak Rahimzadeh

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## Person responsible for updating data

### Contact

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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*