# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

# Investigation of the Efficacy of Intra-articular Prolotherapy With Erythropoietin and Dextrose and Intra-articular Pulsed Radiofrequency on the Primary Osteoarthritis of Knee: Patients' Level of Pain and Knee Joint's Range of Motion

## Protocol summary


**Summary**

Osteoarthritis is one of the most common diseases and knee is the most commonly affected joint. It has been a while that intra-articular prolotherapy is being utilized in acute and chronic pain management . setting. One of the recent methods for treating acute and chronic joint pain is utilization of intra-articular prolotherapy. In this method through insertion of growth stimulants, the inflammatory cascade is activated, which leads to inflammatory factors release, cellular growth and acceleration of cartilage growth. The most commonly used stimulant is dextrose. Nowadays, using different blood components such as platelets and whole blood has been taken into consideration as well. Erythropoietin, released from kidney, a growth stimulant and red blood cells proliferator has stimulus effects on bone marrow cells' growth.Moreover, in several studies pulsed radiofrequency has been reported as a suitable method with minor side effects for treating many painful conditions. Pulsed radiofrequency is a method in which a particular voltage is applied next to the nerve. This study designed to compare the efficacy of the three methods of intra-articular knee joint therapies with prescribing erythropoietin, dextrose, and pulsed radiofrequency to estimate their therapeutic effect and find a more practical solution to more effective pain management while minimizing side effects. Methods and materials: After approval by the ethics committee 70 patients selected. Inclusion criteria were: aged 40-70 ASA I-II, who were suffering from pain in the knee due to primary osteoarthrosis according to the American College of Rheumatology's criteria and had come to the Rasoul Akram pain clinic, if the written conssent signed by them went through one of the treatment methods.First, the patients were examined for pain level based on visual analogue scale (VAS); and the amount of knee joint motion range through goniometric method which were recorded in the pertinent form. Afterwards, the patient was randomly scheduled by the second colleague for one of the aforementioned methods in the operating room using robust (pseudo-) random number generation software. Furthermore, patients' satisfaction was assessed through pre-designed forms before and after prolotherapy and pulsed radiofrequency in weeks 2, 4, and 12. through anteroposterior method from the superolateral part of patella with an angle of about 45 degrees, was entered into the articular area. Erythropoietin group (group 1) receives intra-articular injection of 5 cc of ropivacaine 0.5% together with 4000 international units of erythropoietin .). Dextrose group (group 2) receives fluoroscopically guided intra-articular injection of 5 cc 0.5% ropivacaine together with 5 cc dextrose 25% .. In the pulsed radiofrequency group (group 3), under aseptic conditions and local anestesia with fluoroscopic guidance, through anteroposterior method from the superolateral part of patella with an angle of about 45 degrees, RF needle number 22, 100 millimeter long and 10 millimeter active tip (OWL, Diros Tech, Ontario, Canada) enters the articular area. From the anteroposterior fluoroscopic view the needle tip was embedded at the center of patella. Then, probe (Diros Tech, Ontario, Canada) was entered the articular area and the patients underwent pulsed radiofrequency(20 msec, 2 HZ, 45 V, 15 min,42° C, 2cycles). Following the operation, the patients were transferred to recovery room for one hour to be monitored for any possible side effectsFollowing the operation, the patients transfer to recovery room for one hour to be monitored for any possible side effects, in case there were not any, the patient will discharge. During the second, fourth, and twelfth following weeks they would examined for level of pain according to the expressed pain rate (0 for no pain at all, 10 for worst pain imaginable), and knee joint's motion range was examined through goniometry .

## General information

**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT2013092210336N4**
Registration date: **2013-10-27, 1392/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
**Registration date**
2013-10-27, 1392/08/05

**Registrant information**
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**Recruitment status**
**Recruitment complete**
**Funding source**
Iran University of Medical Sciences

**Expected recruitment start date**
2013-10-23, 1392/08/01
**Expected recruitment end date**
2014-03-21, 1393/01/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigation of the Efficacy of Intra-articular Prolotherapy With Erythropoietin and Dextrose and Intra-articular Pulsed Radiofrequency on the Primary Osteoarthritis of Knee: Patients' Level of Pain and Knee Joint's Range of Motion

**Public title**
Investigation of the Efficacy of Intra-articular Prolotherapy on the Primary Osteoarthritis of Knee: Patients' Level of Pain and Knee Joint's Range of Motion
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
The inclusion criteria were: osteoarthritis according to the American College of Rheumatology's (formerly, American Rheumatology Association) criteria; age 40-70 years old; clinical class I-III; radiology stage 1-3 based on Kellgren-Lawrence criteria. The exclusion criteria were: drugs or alcohol addiction; hemophilia; rheumatoid arthritis or other rheumatologic disease.
**Age**
From **40 years** old to **70 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **70**
**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**
Iran University of Medical Sciences
**Street address**
Cross of Hemmat and Sheykh Fazlollah express way, Tehran
**City**
Tehran
**Postal code**
**Approval date**
2013-07-23, 1392/05/01
**Ethics committee reference number**
13840

## Health conditions studied

**1**

**Description of health condition studied**
knee osteoarthritis
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Knee pain amount
**Timepoint**
Weeks 2, 4 and 12
**Method of measurement**

Visual analogue scale(VAS)

**2**

**Description**
Range of motion of knee
**Timepoint**
Weeks 2, 4 and 12
**Method of measurement**
Goniometry

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Prolotherapy with dextrose
**Category**
Treatment - Drugs

**2**

**Description**
Prolotherapy with erythropoetine
**Category**
Treatment - Drugs

**3**

**Description**
Intraarticular radiofrequency
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Hazrat Rasul Medical Complex
**Full name of responsible person**
**Street address**
**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 Abbas Motevallian
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**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

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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*