

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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 osteoarthritis according to the American College of Rheumatology's criteria and had come to the Rasoul Akram pain clinic, if the written consent 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 anesthesia 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 effects. Following 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 erythropoietine

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

Street address

Cross of Hemmat and Sheykh Fazlollah express way

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

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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