

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Effect of Intra-articular Pulsed Radiofrequency on Pain and Range of Motion in primary Knee Osteoarthritis

Protocol summary

Summary

1) Goals: Our goal in this study is to evaluate the effect of intra-articular radiofrequency use on patients' relief of pain and their degree of change in knee movement. 2) Design: After diagnosing knee osteoarthritis in patients, and ruling out other disorders such as rheumatoid arthritis and hemophilia and opioid or alcohol addiction, the patients will be enrolled in this study. We do not have any age limit for this procedure. We will explain to the patients about the advantages and disadvantages of this intervention which is intra-articular RF and written informed consent is achieved. Then before performing the procedure, the patient's pain with visual analogue score (VAS) and the knee joint ROM would be evaluated and recorded in the questionnaire. After performing the procedure, the patient's pain with VAS and the ROM of the joint plus the amount of used analgesic (400 mg Gelofen if VAS>3) will be assessed again after 1, 4, 8, and 12 weeks. 3) Method: Then the patient would be admitted to the pain OR and under sterile condition after prep-drape on supine position, the RF needle (50 mm) would be inserted under fluoroscopy into the joint and pulsed RF for 15 minutes and 42 degrees will be applied. After being transported to the PACU, the patients would be monitored for one hour regarding complications. 4) The inclusion criteria consist of patients diagnosed as having Knee osteoarthritis; and the other causes of knee pain have been ruled out; The exclusion criteria includes addiction to opium or alcohol ; other rheumatologic disorders ;rheumatoid arthritis; hemophilia 5) Interventions: After performing the intra-articular radiofrequency procedure, the patient's pain with VAS and the ROM of the joint plus the amount of used analgesic(400 mg Gelofen if VAS>3) will be assessed again after 1 , 4, 8, and 12 weeks. 6) Main outcome variables: The pain score (VAS); the joint's ROM; and the amount of analgesic use by the patients are our main outcome variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306307984N11**

Registration date: **2013-08-04, 1392/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-08-04, 1392/05/13

Registrant information

Name

Farnad Imani

Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

The Vice chancellor for research, tehran university of medical sciences

Expected recruitment start date

2012-05-09, 1391/02/20

Expected recruitment end date

2014-05-10, 1393/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Intra-articular Pulsed Radiofrequency on Pain and Range of Motion in primary Knee Osteoarthritis

Public title

Effect of Intra-articular Pulsed Radiofrequency on Pain and Range of Motion in primary Knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria consist of patients diagnosed as having Knee osteoarthritis; and the other causes of knee pain have been ruled out; The exclusion criteria includes addiction to opium or alcohol ; other rheumatologic disorders ;rheumatoid arthritis; hemophilia

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Tehran university of medical sciences

Street address

The ethics committee of Tehran university of medical sciences, Poursina St., Tehran

City

Tehran

Postal code

Approval date

2012-04-11, 1391/01/23

Ethics committee reference number

90-01-30-12978-48017

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

unilateral Primary gonarthrosis

Primary outcomes

1

Description

Pain score (VAS)

Timepoint

First, fourth, and twelfth weeks after the intervention

Method of measurement

Visual analogue score

Secondary outcomes

1

Description

The knee joint range of motion (ROM)

Timepoint

1st, 4th, and 12th weeks after the intervention

Method of measurement

Goniometry

2

Description

The amount of used analgesic

Timepoint

1st, 4th, and 12th weeks after the intervention

Method of measurement

The miligram dose of the analgesics

Intervention groups

1

Description

Pulsed radiofrequency of the knee joint at 42 degrees of centigrade and 15 minutes

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Dr Farnad Imani

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Full name of responsible person

Dr Akhundzadeh

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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, Tehran 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**

Rasoul Akram Medical Center

Full name of responsible person

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Position

Associate professor

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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