Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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 rheumatalogic 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
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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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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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

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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