

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The comparison of two therapeutic methods, Radiofrequency and Ozone therapy in knee osteoarthritis

Protocol summary

Summary

This study is to compare two new therapeutic methods of radiofrequency and intraperiarticular ozone injection to improve knee function osteoarthritis (OA). The patients between 30 -70 years old with moderate to severe knee pain at least for 3 months with no response to usual conservative treatments and not appropriate candidates for surgery enrolled to the study. They are divided in two groups Radiofrequency (RF) and ozone (O) by triple blocks. In RF group after diagnostic genicular nerve block and sensory and motor testing undergoing to conventional radiofrequency and then intra articular pulse radiofrequency and in (O) group received intra and periarticular ozone injection. The evaluation of pain severity and knee function is based on VAS and Oxford Knee Score (OKS) that is filled before and 12 weeks after treatment. Outcome is improved knee function in osteoarthritis disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412156186N6**
Registration date: **2015-01-17, 1393/10/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-01-17, 1393/10/27

Registrant information

Name

Bahram Naderi Nabi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-01-10, 1393/10/20

Expected recruitment end date

2015-04-21, 1394/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of two therapeutic methods,
Radiofrequency and Ozone therapy in knee osteoarthritis

Public title

The comparison of two therapeutic methods,
Radiofrequency and Ozone therapy in knee osteoarthritis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the patients between 30 to 75 years old; moderate to severe knee pain; at least for 3 months with no response to usual conservative treatments.

Exclusion criteria: intraarticular steroid injection during the previous 3 months; secondary osteoarthritis; sciatic pain.

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

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 Guilan university of Medical Science

Street address

Namjoo Street

City

Rasht

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4193893345

Approval date

2014-08-19, 1393/05/28

Ethics committee reference number

1930231625

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M19.0

ICD-10 code description

Primary arthrosis of other joints

Primary outcomes

1

Description

Pain

Timepoint

Before treatment and twelve weeks after treatment

Method of measurement

Visual Analog Scale (VAS); Questionnaire

2

Description

Knee function

Timepoint

Before treatment and 12 weeks after treatment

Method of measurement

Oxford Knee score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention1: Ozone group, ozone group patients received intra articular ozone injection (10 cc O2-O3 mixture 40µg/ml) and periarticular injection (5 cc O2-O3 mixture 10µg/ml) by Ozone Generator HERRMANN.

Category

Treatment - Other

2

Description

Intervention2: Radiofrequency group, Diros3AP RF generator rissing electrode tip temperature to 70°C for 90 seconds The procedure was carried out for each genicular nerve and then intra-articular PRF having a pulse width of 10 milliseconds at 2 HZ and 65 volt.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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Shahid beheshti Highway

City
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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 of Guilan 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