# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

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

## 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
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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 ostheoartritis

**Public title**

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

**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
**Postal code**
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 generatorrising 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**
Bahram Naderi Nabi
**Street address**
Parastar Street
**City**
Rasht

## 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
**Street address**
Shahid beheshti Highway

**City**
Rasht
**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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## Person responsible for updating data

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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*