

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Radiofrequency and intraarticular ozone on improving the osteoarthritis symptoms of knee joint

Protocol summary

Study aim

Determining the effect of radiofrequency with intra-articular ozone on the symptoms of osteoarthritis of the knee joint

Design

Clinical trial with 2 groups ozone and radiofrequency, single blind, randomized trial

Settings and conduct

This study will be performed as a single-blind randomized clinical trial in Imam Reza Hospital on patients with osteoarthritis of the knee. A total of 70 patients with inclusion criteria are first examined by a colleague for pain intensity and limited mobility of the knee and the result is recorded. The patient is then referred to the project colleague to be randomly assigned to one of two groups of 35-frequency radiofrequency or ozone. At the end of the treatment period, the patient is re-examined and the result is recorded by the same colleague who is blind to the treatment method. At the end, the results of the therapeutic intervention in improving the disease are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Median knee osteoarthritis (Grade 2 or 3 based on Kellgren and Lawrence knee radiography); Patients over 45 years old; Satisfaction of patients participating in the study; Exclusion criteria: Severe osteoarthritis; Rheumatic disease; Received previous corticosteroids 3 months ago; Clearly visible deformity of the varus or valgus of the knee; Severe knee flexion contraction; Psychological disorders; Drug dependence; Pregnancy.

Intervention groups

First Intervention group (ozone therapy): In this group, patients undergoing ozone therapy with ozone gas at 15 cc with a concentration of 35 microcc per cc twice a week; They will be in total for 4 sessions. Intervention group 2 (radiofrequency group): In this group, patients will be exposed to PRF once a week for 2 sessions at a

temperature of 42 ° C and a pulse width of 20 milliseconds, 2 Hz for 15 minutes.

Main outcome variables

Physical function, pain, patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180518039700N3**

Registration date: **2021-09-12, 1400/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-12, 1400/06/21**

Update count: **0**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Solmaz Fakhari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3329 6124

Email address

fakharis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Radiofrequency and intraarticular ozone on improving the osteoarthritis symptoms of knee joint

Public title

Comparison of radiofrequency with ozone in improving the symptoms of knee osteoarthritis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Median knee osteoarthritis (Grade 2 or 3 based on Kellegren and Lawrence knee radiography) Patients over 45 years old Satisfaction of patients participating in the study Failure to respond to conservative and physiotherapy treatments over the past 6 months

Exclusion criteria:

Severe osteoarthritis (Grade 4 candidates for joint replacement surgery) Rheumatic disease Received previous corticosteroids 3 months ago Clearly visible deformity of the varus or valgus of the knee Severe knee flexion contraction Ankylosis Psychological disorders Drug dependence Hyperthyroidism Thrombocytopenia Pregnancy

Age

From **45 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Using GraphPad online randomization software (<https://www.graphpad.com/quickcalcs/randomize1>), 70 patients will be randomly allocated into two groups (n=35) A (ozone group) and B (radio-frequency group). According to this list, the patients referred to the study will be considered as group A or B, respectively. In the ozone group, intra-articular injection of ozone and in the radio-frequency group, radio frequency therapy will be applied intra-articularly.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is single blinded study and in this trial 70 patients with study inclusion criteria, first examined by one of coworkers due to knee pain and functional limitation, and the results are recorded. The patients are referred to the principle investigator and they randomly assigned to one of the two groups; Radiofrequency or

ozone (n=35). At the end of the treatment, the patients will be examined again by the same coworker, who will be kept blind to the treatment, and the result is recorded. At the end of the study, the two groups will be compared due to their pain and functional status.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2021-01-25, 1399/11/06

Ethics committee reference number

IR.TBZMED.REC.1399.1022

Health conditions studied**1****Description of health condition studied**

knee osteoarthritis

ICD-10 code

M15.0

ICD-10 code description

Primary generalized (osteo)arthritis

Primary outcomes**1****Description**

Physical performance

Timepoint

At the beginning of the study, in 4th session of ozone therapy and 2nd session of radio frequency (at the end of sessions of both methods) and one month after the end of sessions.

Method of measurement

WOMAC questionnaire(Western Ontario and McMaster Universities Osteoarthritis Index questionnaire)

2

Description

Intensity of pain

Timepoint

At the beginning of the study, in 4th session of ozone therapy and 2nd session of radio frequency (at the end of sessions of both methods) and one month after the end of sessions.

Method of measurement

VAS (Visual Analog Scale) will be measured at rest and after 6 meters of walking.

3

Description

Patient satisfaction

Timepoint

At the beginning of the study, in 4th session of ozone therapy and 2nd session of radio frequency (at the end of sessions of both methods) and one month after the end of sessions.

Method of measurement

Question from the patient (excellent, good, acceptable and unsatisfactory)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ozone group: 15 cc of ozone 35 micro-grams per millilitre will be injected. After injection, flexion and extension movements will be performed for better distribution of gas in the knee. When finished, the place is bandaged and it is transferred to the recovery and stays in the recovery for 30 minutes, then it is transferred to the ward and will be released after 4 hours. This action will be done twice a week for a total of 4 sessions.

Category

Treatment - Drugs

2

Description

Intervention group: Radiofrequency group: Radiofrequency needle with 100 mm length and 10 mm active tip is inserted into the joint, then PRF with a temperature of 42 ° C and a pulse width of 20 milliseconds, 2 Hz is applied for 15 minutes. This action is done twice. It is done in 2 weeks (once a week).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Tabriz University of Medical Sciences

Full name of responsible person

Solmaz Fakhari

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Imam Reza Hospital, Golgasht St., Azadi Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Joiban

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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

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Solmaz Fakhari

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All potential data can be shared after making peoples unrecognizable

When the data will become available and for how long

Starting 6 months after publication.

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data

From where data/document is obtainable

Dr .Solmaz Fakhari , Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 ,

solmaz_fakhari@yahoo.com

What processes are involved for a request to access data/document

Applicants will access the data from the present study by

sending an email to the responsible author for a maximum of one week.

Comments