

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparative effect of intra-articular Ozone injections with suprapatellar lateral and inferomedial approaches for pain control in patients with knee osteoarthritis

Protocol summary

Study aim

Comparative effect of intra-articular Ozone injections with suprapatellar lateral and inferomedial approaches for pain control in patients with knee osteoarthritis

Design

Double blind randomized clinical trial with control group, 60 patients sample size, Trial phase 2-3

Settings and conduct

In the tertiary regional and teaching hospital, among patients, candidates for ozone injection with suprapatellar lateral and inferomedial approaches refer to the Akhtar Hospital, after randomization, all procedures are performed using spinal needle 27 Gage. With ultrasonography guidance, 10 ml of ozone (15 µg / ml) is injected. Ozone injection is given up to three weeks, once a week. In these patients, pain in the portal area is measured by VAS (0-10). Disability based on Knee injury and Osteoarthritis Outcome Score questionnaire, is measured, which is completed in two steps before the start of treatment and three months after the last injection by the patient. Patients are asked to determine their pain levels before, one month and three months after the last injection. Complications are recorded.

Participants/Inclusion and exclusion criteria

Major eligibility criteria: Patients older than 40 years; The pain of knee osteoarthritis. Major exclusion criteria: Degenerative Disc Herniation; History of Lumbar Spine Surgery

Intervention groups

Control group (inferomedial): The patient is placed in a supine position, It is characterized by knee flexion of about 45 to 30 degrees on the lateral side of the knee, landmark of the injection area is determined.
Intervention group (suprapatellar lateral): The patient is placed in a supine position, Insert the needle one centimeter high and one cm in the lateral portion of the super pellet margin with an angle of 45 ° in the direction

of the cephalo lateral to the quadromedial, landmark of the injection area is determined.

Main outcome variables

Pain Level; Disability.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131124015515N5**

Registration date: **2019-03-14, 1397/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-14, 1397/12/23**

Update count: **0**

Registration date

2019-03-14, 1397/12/23

Registrant information

Name

Masoud Hashemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 2252

Email address

dr.hashemi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-10, 1397/12/19

Expected recruitment end date

2019-07-20, 1398/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect of intra-articular Ozone injections with suprapatellar lateral and inferomedial approaches for pain control in patients with knee osteoarthritis

Public title

The effect of ozone injection with two different injection methods to control knee pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients older than 40 years The pain of knee osteoarthritis for more than three months Radiological findings confirming knee osteoarthritis based on the American College of Rheumatology Osteoarthritis with Grade II-III based on Kellgren-Lawrence radiology grading No effusion Signed written informed consent to participate in the study

Exclusion criteria:

Patients with history of knee surgery Deformity and lower limb contraction Lower limb neovascular disease Acute lumbosacral pathology Injection of steroid drugs over the past two months History of inflammatory rheumatoid arthritis Infection Diabetes Pregnancy Breast feeding Body Mass Index >35 kg/m² Patients undergoing knee surgery Knee deviation (verrucous or valgus more than 5 degrees) confirmed by three joint view Radicular pain Knee pain Anticoagulant therapy Post-traumatic arthritis History of intraArticular or ozone therapy during 12 Last month Systemic or psychiatric illness Severe osteoarthritis with Grade over III

Age

From **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization based on random numbers table

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and clinical outcomes evaluator are not aware of the code assigned to each of the groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services

Street address

Tabnak St.,Tehran, Tehran, Iran, Islamic Republic Of

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-06-29, 1397/04/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.286

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

Knee Osteoarthritis

ICD-10 code

M17.10

ICD-10 code description

Unilateral primary osteoarthritis, unspecified knee

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

Pain Level by visual analog scale

Timepoint

In the portal area during the first, second, third and fourth injections and knee pain before treatment, one month and three months after the last injection

Method of measurement

Visual analog scale (VAS) (0 None; 1-3 Mild; 4-7 Moderate; 8-10 Severe)

2**Description**

Disability Level by Oswestry Low Back Disability Questionnaire

Timepoint

Before starting treatment and three months after the last injection

Method of measurement

Oswestry Low Back Disability Questionnaire that disability is measured with 10 items. Each item is scored from 5-0, which indicates a higher score for the disability.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: suprapatellar lateral approach, the patient is placed in a supine position, Insert the needle one centimeter high and one cm in the lateral portion of the super pellet margin with an angle of 45 ° in the direction of the cephalo lateral to the quadomedial, landmark of the injection area is determined.

Category

Treatment - Other

2

Description

Control group: Inferomedial approach, the patient is placed in a supine position, It is characterized by knee flexion of about 45 to 30 degrees on the lateral side of the knee, landmark of the injection area is determined.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhtar Hospital

Full name of responsible person

Seyed Masoud Hashemi MD

Street address

Pain Clinic, Akhtar Hospital, Sharifi Manesh st.

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Fax

+98 21 2260 8246

Email

dr.hashemi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi MD

Street address

Shahid Arabi st., Yaman St., Shahid Chamran Expressway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Masoud Hashemi MD

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Akhtar Hospital, Sharifi Manesh st

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dr.hashemi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Masoud Hashemi MD

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Akhtar Hospital, Sharifi Manesh st.

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Fax**Email**

dr.hashemi@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Masoud Hashemi MD

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Akhtar Hospital, Sharifi Manesh st.

City

Tehran

Province

Tehran

Postal code

1964714953

Phone

+98 21 2261 2252

Email

dr.hashemi@sbmu.ac.ir

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

The whole data can be shared after unidentifiable people.

When the data will become available and for how long

Start the access period 12 months after printing the results

To whom data/document is available

Only available to scholars working in academic and academic institutions

Under which criteria data/document could be used

Employed in research centers

From where data/document is obtainable

Person responsible for scientific inquiries

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

Send email to person responsible for scientific inquiries

Comments