

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparison between clinical effects of intra-articular ozone and intra-articular steroid injection in the treatment of chronic ankle osteoarthritis

Protocol summary

Study aim

Comparison between effects of intra-articular injection of corticosteroid and ozone on pain and function of ankle in osteoarthritis of ankle

Design

The randomized trial, parallel groups; single-blind, 40 patients, phase 2-3, using permuted block randomization.

Settings and conduct

5 cc of ozone with a concentration of 30 micrograms per milliliter was injected into the joint. Ozone injections were once a week for 3 weeks. In corticosteroid group we injected 40 mg triamcinolone. The injection site was Mortis ankle joint Patient's position was supine and ankle was in neutr position . In the ozone therapy group before the start of the study, at the end of the third session, one month after and 6 months after the end of the ozone therapy sessions, and in the steroid therapy group before the start of the study, one month after the methylprednisolone injection and 6 months after the injection , The following items were recorded for each patient: Pain by theoretical analog scale (VAS) 2) FADI) Foot And Ankle Disability Index)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate ankle osteoarthritis, Existence of symptoms of ankle osteoarthritis for at least 3 months, Minimum score of 3 in (VAS) criteria, Absence of inflammatory rheumatic diseases, Aged 45 years and older; Failure in conservative medication and physiotherapy treatments during the past 6 months. Exclusion criteria: Severe osteoarthritis, Rheumatic disease, Clearly visible deformity of the ankle, Ankylosis, Ozone contraindications, Definitive and relative contraindications to steroid injection, Artificial joint, Uncontrolled coagulation disorders, Specific skin lesion at the injection site.

Intervention groups

1.Corticosteroid therapy 2.Ozone therapy

Main outcome variables

Function of ankle; Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100827004641N19**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **retrospective**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

Bina Eftekharsadat

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2021-02-20, 1399/12/02

Actual recruitment start date

2019-11-03, 1398/08/12

Actual recruitment end date

2020-03-11, 1398/12/21

Trial completion date

2021-09-04, 1400/06/13

Scientific title

Comparison between clinical effects of intra-articular ozone and intra-articular steroid injection in the treatment of chronic ankle osteoarthritis

Public title

Comparison between clinical effects of intra-articular ozone and intra-articular steroid injection in the treatment of chronic ankle osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Existence of symptoms of ankle osteoarthritis for at least 3 months Minimum score of 3 in the criterion (VAS) Absence of inflammatory rheumatic diseases Failure to respond to conservative drug and physiotherapy treatments during the past 6 months Satisfaction of patients participating in the study rug and physiotherapy treatments during the past 6 months Aged 45 years and older

Exclusion criteria:

Severe osteoarthritis (Grade 4 candidates for joint replacement surgery) Rumatic disease Clearly visible deformity of the ankle Ankylosis Ozone contraindications include: -Hyperthyroidism -Thrombocytopenia -Pregnancy Recent history of heart attack G-6PD deficiency Definitive and relative contraindications to steroid injections include: Bacteremia, sepsis, intra-articular or pre-uricular infection, history of post-injection allergies Specific skin lesion at the injection site

Age

From **45 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation was performed using block randomization using software (RAS). The size of the blocks is 4, which includes an equal number of each intervention with a 1: 1 allocation ratio. Blocking is done by a person not involved in sampling and data analysis. To hide the allocation, the type of intervention was written on a piece of paper using the letters A and B and placed in matte and numbered envelopes. The envelopes were given to the participants in the order of the participants.

Blinding (investigator's opinion)

Single blinded

Blinding description

It was not possible to blind patients due to the difference in the injection material, so the volunteers were aware of what treatment method was used in each group. The injections were performed by a physical medicine specialist. Data researchers, data analyzers, and outcome evaluators were blind. They were not aware of the intervention performed on each group of patients. Only the final data in the form of the first and second groups and random numbers assigned to each patient was available.

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

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Golgasht Avenue

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Approval date

2021-10-12, 1400/07/20

Ethics committee reference number

IR.TBZMED.REC.1400.623

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

Chronic Osteoarthritis of Ankle

ICD-10 code

M19.079

ICD-10 code description

Primary osteoarthritis, unspecified ankle and foot

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

The amount af Reduce in pain after injection

Timepoint

1 month after injection and 6 months after injection

Method of measurement

FADI questionnaire

Secondary outcomes**1****Description**

Improvement of function and reduce in pain of ankle

Timepoint

Before, 1 month and 6 months after injection

Method of measurement

FADI questionnaire

Intervention groups**1****Description**

Intervention group: corticosteroid injection: mixture of 40 mg of triamcinolone and 1 mg of lidocaine 2% was injected. Mortis joint was the site of injection. On the inter-malleolar line, we entered the ankle joint space in 2 inches medial to the lateral malleolus. With Needle 23 in the steroid therapy group before the start of the study, one month after the methylprednisolone injection and 6 months after the injection, the following items were recorded for each patient: Pain by the theoretical analog standard (VAS) 2) FADI Foot And Ankle Disability Index)

Category

Treatment - Other

2**Description**

Intervention group: ozone injection: 5 cc ozone with a concentration of 30 micrograms per ml with half a cc of 2% lidocaine was injected into the joint. Ozone injections were given to each patient once a week for 3 sessions. Mortis joint was injection site. Patient was in the supine position and the ankle was in the neutral position. In the sterile condition through the dorsal depression of the ankle on the intermalleolar line in 2 inches medial to the lateral malleolus entered the joint space. With Needle 23 in the ozone therapy group before the start of the study, at the end of the third session, one month later and 6 months after the end of the ozone therapy sessions, the following items are recorded for each patient: Pain by Theoretical Analogue Criterion (VAS) 2) FADI Foot And Ankle Disability Index)

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Physical Medicine and Rehabilitation Research Center of Tabriz

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

Physical Medicine and Rehabilitation Research Center of Tabriz

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

Bina Eftekharsadat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available