Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparıson between clınıcal effects of ıntra-artıcular ozone and intra-articular steroıd injection ın the treatment of chronic ankle osteoarthrıtıs

Protocol summary

Study aim

Comparsion 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 teriamcinolon. 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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+98 41 1330 3193
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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
Comparıson between clınıcal effects of ıntra-artıcular ozone and intra-articular steroıd injection ın the treatment of chronic ankle osteoarthrıtıs

Public title
Comparıson between clınıcal effects of ıntra-artıcular ozone and intra-articular steroıd injection ın the treatment of chronic ankle osteoarthrıtıs
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
Street address
Golgasht Avenue
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Tabriz
Province
East Azarbaijan
Postal code
5166616471
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 Osteoartritis 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 an 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 join was the dite of injection. On the inter-maleular line, we entered the ankle joint space in 2 inches medial to the lateral maleus. 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 intermalleular line in 2 inches medial to the lateral maleus 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
Dr. Bina Eftekharsadat
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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
Yaghoub Salek Zamani
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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
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Person responsible for updating data

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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