Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparition the impact of intraarticular Steroid and intraarticular ozon on improving the symptoms of osteoarthritis of knee

Protocol summary

Study aim
Comparison of Clinical effects of Steroids and Intra articular Ozone in improving the symptoms of Chronic Knee Osteoarthritis

Design
The clinical trial consisted of two groups of Steroid therapy and Ozone therapy Randomised with parallel group trial and phase 2-3 ,single blind groups on 40 patients and randomization based on a random number table and RAS software.

Settings and conduct
In the ozone therapy group, 5 cc of ozone with a concentration of 30 micrograms per ml with 2 cc of lidocaine 2% will be injected into the joint.The injection will be performed in the physical medicine clinic of Imam Reza Hospital.In the steroid therapy group, patients treated with a mixture of 40 mg triamcinolone and 1 mg lidocaine 2% will be given intra-articular onceThe study is single blind because it is not possible to blind patients due to the difference in the injectable material.The researcher and data analyzer are blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Moderate Knee Osteoarthritis Existence of symptoms in favor of Knee Osteoarthritis for at least 3 months Minimum score 3 in the criterion (VAS) Absence of inflammatory Rheumatic diseases Patients over 45 years Satisfaction of patients Failure to respond to Conservative treatments Exit criteria: Severe stevoarthritis Rheumatic disease Clearly visible deformity of the Knee Ankylosis Contraindications to Ozone and Steroid

Intervention groups
Steroid therapy group and Ozone therapy group

Main outcome variables
The amount of Reduce in pain after injection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100827004641N18**
Registration date: **2021-11-17, 1400/08/26**
Registration timing: **retrospective**

Last update: **2021-11-17, 1400/08/26**
Update count: **0**

Registration date
2021-11-17, 1400/08/26

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
Comparition the impact of intraarticular Steroid and intraarticular ozon on improving the symptoms of

osteoarthritis of knee

Public title
Comparition the impact of Steroid and intraarticular ozon on improving the symptoms of osteoarthritis of knee
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Moderate Knee Osteoarthritis (grade two or three based Radiographic classification (Kellegren and Lawrence) Existence of symptoms in favor of Knee Osteoarthritis for at least 3 months Minimum score of 3 in the criterion (VAS) Absence of Inflammatory Rheumatic diseases 45 years old and older Satisfaction of patients participating in the study Failure to respond to Conservative drug treatments and physiotherapy lasted for 6 months
Exclusion criteria:
Severe Osteoarthritis (grade 4 candidates for joint replacement surgery) Rheumatic disease Clearly Visible deformity of the knee Ankylosis Contraindications to Ozone include: Hyperthyroidism , Thrombocytopenia ,Pregnancy , Recent heart attack history ,G6PD Deficiency Definitive and partial Contraindications to Steroid injection include: Bacteremia, Sepsis, Intra articular or pre uricular infection, History of post injection Allergy, Intra articular or Osteochondral fracture at the injection site, Severe Joint destruction in Injection site , Artificial joint , Uncontrolled Coagulation disorders 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
Participants will be assigned to either the steroid or ozone injection groups using block randomization using random allocation software (RAS). The size of blocks is 4 including the equal numbers of each intervention of the study in each block and a 1:1 assignment ratio. Blocking will be performed by the non-involved person in data sampling and analysis. To conceal the assignment, the type of intervention will be written on a sheet of paper coding using the letters A and B and placed inside matted, consecutively numbered envelopes. The envelopes will be arranged according to the participants' entry to the intervention, and the type of group will be revealed.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study was single blind because it was not possible to blind patients due to the difference in the injection material and the volunteers will be aware of what treatment method was used in each group.The injections were performed by a physical medicine specialist.The researcher and the person conducting the follow up and data analysts and outcome assessors who are blinded and unaware of the intervention performed on each group of patients And only the final data in the form of the first and second groups and random numbers assigned to each patient will be 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
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2021-10-04, 1400/07/12
Ethics committee reference number
IR.TBZMED.REC.1400.622

Health conditions studied

1

Description of health condition studied
استئو آرتریت مزمن زانو
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
The amount af Reduce in pain after injection
Timepoint
Immediately before injection and 1 month after injection

and 6 months after injection

Method of measurement

Western Ontario and McMaster Universities Arthritis Index (WOMAC)questionare

Secondary outcomes

1

Description

Improvement of function of Knee

Timepoint

Immediately before injection and one and six months after injection

Method of measurement

Western Ontario and McMaster Universities Arthritis Index (WOMAC)questionare

Intervention groups

1

Description

Intervention group: In the ozone therapy group, 5 cc of ozone with a concentration of 30 micrograms per ml with 2 cc of 2% lidocaine will be injected into the joint. Ozone injections will be given to each patient once a week for 3 sessions. Consumable ozone is produced by Palaguar ozone generator, the exclusive representative of the German company Herrmann.

Category

Treatment - Drugs

2

Description

Intervention group: In the steroid therapy group, patients treated with a mixture of 40 mg triamcinolone and 1 mg lidocaine 2% will be given intra-articular once. Triamcinolone is consumed by Iran Hormone Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Physical medicine clinic of Imam Reza Hospital

Full name of responsible person

Dr. Bina Eftekharsadat

Street address

Department of Physical Medicine and rehabilitation, Imam Reza Hospital, Daneshgah Square, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Physical Medicibe and Rehabilitaion Research Center of Tabriz

Full name of responsible person

Yaghoub Salek Zamani

Street address

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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 Medicibe and Rehabilitaion 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

Dr. Bina Eftekharsadat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Dr. Bina Eftekharsadat
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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available