Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of combination of periarticular dextrose prolotherapy and ozone, on pain reduction in patients suffering from knee osteoarthritis

Protocol summary

Study aim
The effect of combination of periarticular dextrose prolotherapy and ozone, on pain reduction in patients suffering from knee osteoarthritis.

Design
This clinical trial is performed on 28 patients in 2 groups. This study is a single-blind randomized clinical trial and random blocking method has been done in this study.

Settings and conduct
The field of work is clinical - internal. The study is performed in the special clinic of Kurdistan University of Medical Sciences. This study is a single-blind randomized clinical trial. Participants are not blind to the intervention, given that the injection is given in one of the individual's knees but colleagues who evaluate the outcomes of the study are blind to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with grade 2 and 3 osteoarthritis of both knees, Age over 50 years, Morning stiffness less than 30 minutes, Crepitus in active knee movements, Bone sensitivity. Non-inclusion criteria: Injection of steroid drugs in the last 2 months, Diabetes, Indication for surgical arthroplasty, Previous injection treatment with dextrose, Knee inflammation, Daily use of drugs, Malignancy, Grade 4 osteoarthritis

Intervention groups
Patients are divided into two groups according to the injection in the knee, compared to each other. Group A (injection around the right or left knee) and group B (no injection around the right or left knee). The amount of injection is 8 ml of 5% dextrose and 2 ml of 1% lidocaine and 5 ml of ozone. Three injections are given at weekly intervals for each patient. There is no separate control group in this study and each person will be in control of himself.For each person, the injection is given in only one knee and the other knee is used as the control.

Main outcome variables
Intensity of pain, Physical function, Kellgrn lawrence index, Possible side effects

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190415043279N8**
Registration date: **2020-12-11, 1399/09/21**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-11, 1399/09/21**
Update count: **0**

Registration date
2020-12-11, 1399/09/21

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of combination of periarticular dextrose prolotherapy and ozone, on pain reduction in patients suffering from knee osteoarthritis

Public title
The effect of periarticular dextrose prolotherapy and ozone on knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with grade 2 and 3 osteoarthritis of both knees Age over 50 years Morning stiffness less than 30 minutes Crepitus in active knee movements Bone sensitivity Bone enlargement Lack of heat in the joint touch
Exclusion criteria:
Injection of steroid drugs in the last 2 months Diabetes Indication for surgical arthroplasty Previous injection treatment with dextrose Knee infection in the last three months Knee inflammation Daily use of drugs History of inflammatory joint disease Arthritis after infection Joint dysplasia Congenital anomalies Crystalopathy Arthritis after injury Malignancy Vascular necrosis Obesity Grade 4 osteoarthritis
Age
From **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **28**
Randomization (investigator's opinion)
Randomized
Randomization description
The placement of individuals will be in each of the intervention (injection in one of the right or left knee) and control (no injection in the opposite knee) groups. In the form of random quadruple blocks B, B, A, A are assigned to two random groups. Group A patients (injection around the right knee) and group B patients (injection around the left knee). The selection of the samples will be as the following arrangement: ABBA BBAA BABA AABB BAAB BAAB AABB ABAB AABB BAAB BAAB ABBA ABAB.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single-blind randomized clinical trial. In fact, there is no separate control group in this study and each person will be in control of himself. For each person, the injection is given in only one knee and the other knee as a control. Participants are not blind to the intervention because the injection is given in one of the person's knees but colleagues who evaluate the outcome of the study are blind to the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan University of Medical Sciences
Street address
Kurdistan University of Medical Sciences; Pasdaran Blvd.
City
Sanandaj
Province
Kurdistan
Postal code
66117713446
Approval date
2020-10-13, 1399/07/22
Ethics committee reference number
IR.MUK.REC.1399.171

Health conditions studied

1

Description of health condition studied
knee arthritis
ICD-10 code
M17.0
ICD-10 code description
Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description
Intensity of pain
Timepoint
Before intervention, one month after intervention, two months after intervention
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Physical function
Timepoint
Before intervention, one month after intervention, two months after intervention
Method of measurement
WOMAC Index

3

Description
Kellgrn lawrence index
Timepoint
Before intervention, one month after intervention, two months after intervention
Method of measurement
Radiological imaging

Secondary outcomes

1

Description
Possible side effects
Timepoint
During the treatment period until the end of the intervention
Method of measurement
Any possible side effects such as pain, swelling, itching, redness and warmth at the injection site are measured and recorded.

Intervention groups

1

Description
Intervention group: Injection into one of the joints, The amount of injection is 8 ml of 5% dextrose and 2 ml of 1% lidocaine and 5 ml of ozone. Three injections are given at weekly intervals for each patient.
Category
Treatment - Other

2

Description
Control group: No injection in the opposite knee
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Special clinic of Kurdistan University of Medical Sciences
Full name of responsible person
Dr Nasrin Moghimi
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Sponsors / Funding sources

1

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Name of organization / entity
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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
Sanandaj 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available