

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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

##### Name

Pezhman Sharifi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3324 9435

##### Email address

p.sharifi@muk.ac.ir

##### 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 AAB ABAB AAB 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

##### **Street address**

Tohid Hospital, Tohid Blvd

##### **City**

Sanandaj

##### **Province**

Kurdistan

##### **Postal code**

6616813131

##### **Phone**

+98 87 3328 6112

##### **Email**

Nasrin\_43ir@yahoo.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Sanandaj University of Medical Sciences

##### **Full name of responsible person**

Dr. Afshin Maleki

##### **Street address**

Vice Chancellor for Research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

##### **City**

Sanandaj

##### **Province**

Kurdistan

##### **Postal code**

6617713466

##### **Phone**

+98 87 3366 4645

##### **Email**

maleki43@yahoo.com

#### **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**

##### **Name of organization / entity**

Sanandaj University of Medical Sciences

##### **Full name of responsible person**

Dr Nasrin Moghimi

##### **Position**

Assistant Professor

##### **Latest degree**

Subspecialist

##### **Other areas of specialty/work**

Internal Medicine

##### **Street address**

Tohid Hospital, Tohid Blvd

##### **City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 3366 4645

**Email**

Nasrin\_43ir@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Dr Nasrin Moghimi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Tohid Hospital, Tohid Blvd

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6617713446

**Phone**

+98 87 3366 4645

**Email**

Nasrin\_43ir@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Pezhman Sharifi

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Microbiology

**Street address**

Research Department, Tohid Hospital, Tohid Blvd

**City**

Sanandaj

**Province**

Kurdistan

**Postal code**

6616813131

**Phone**

+98 87 3324 9435

**Fax**

+98 87 3324 9435

**Email**

p.sharifi@muk.ac.ir

**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