

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Investigating the early effect of hypertonic dextrose on the pain level and movement status of patients with chronic osteoarthritis of the knee compared to corticosteroids

#### Protocol summary

##### Study aim

Investigating the early effect of hypertonic dextrose on the pain level and movement status of patients with chronic osteoarthritis of the knee compared to corticosteroids

##### Design

This study will be a randomized clinical trial (blocks of four) and double-blind (patient and data analyst), phase 2-3, with parallel groups and with the participation of 62 patients with knee osteoarthritis. Patients will be divided into two groups.

##### Settings and conduct

This randomized and double-blind clinical trial study (patients and data analysts) will be conducted with the participation of patients with symptoms of knee arthritis who will refer to Imam Hossein Hospital. Under ultrasound guidance, a 22G needle is inserted from the lateral part of the outer part of the knee, and triamcinolone (40 mg) or dextrose 20% (5 cc) drugs will be injected into the knee joint, and the pain intensity after one month of the intervention between two The group will be compared.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria for this study include: suffering from knee osteoarthritis, ages between 40 and 80 years, Grade II arthrosis and mobility limitation, and the exclusion criteria for this study include: pregnancy, use of anticoagulants, infection at the injection site, history of severe knee trauma, history of knee surgery and diabetes mellitus.

##### Intervention groups

In this randomized and double-blind clinical trial study, 62 patients will be randomly assigned to two groups of dextrose or corticosteroid injections in the knee joint, and their pain intensity will be measured after the completion of the intervention (three months).

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190325043107N32**

Registration date: **2023-04-22, 1402/02/02**

Registration timing: **prospective**

Last update: **2023-04-22, 1402/02/02**

Update count: **0**

##### Registration date

2023-04-22, 1402/02/02

##### Registrant information

##### Name

Mehdi Khanbabayi Gol

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 7054

##### Email address

khanbabayimehdi69@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-19, 1402/02/29

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Investigating the early effect of hypertonic dextrose on the pain level and movement status of patients with chronic osteoarthritis of the knee compared to corticosteroids

**Public title**

Comparison of hypertonic dextrose with corticosteroids on pain and motor status of chronic knee osteoarthritis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Knee osteoarthritis Arthritis grade II Movement restriction Ages between 40 and 80 years

**Exclusion criteria:**

Pregnancy Taking anticoagulants Infection at the injection site History of severe knee injury History of knee surgery Having diabetes mellitus

**Age**

From **40 years** old to **80 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, the block random division method (blocks of 4) is used. One of the colleagues of the study, who was not blinded, names the dextrose treatment method with the letter A and the corticosteroid method with the letter B. Then, the researcher distributes packages A and B among the referring patients in order to participate in the study using a block random division method (of 4). Then, among the created blocks, so many blocks are randomly selected to reach the required sample size. To make a random sequence, we give numbers from 1 to 16 to the possible blocks (16 blocks). According to the sample size, any number of 4 blocks will be used. Block numbers will be selected from the table of random numbers and the sequence of blocks in each group will be determined based on these numbers. Finally, with the help of 16 blocks of four, random allocation will be done.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The statistical consultant and the patient will be unaware of the type of grouping in this plan; The final results will be delivered to the statistical consultant. Since the statistical consultant and the patients will not be aware of the grouping of the participants; Therefore, they are blind during the study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research ethics committees of vice-chancellor in research affairs Shahid Beheshti University of Medi

**Street address**

Tehran, Evin, Shahid Shahriari Square

**City**

Tehran

**Province**

Tehran

**Postal code**

5165665631

**Approval date**

2023-04-15, 1402/01/26

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1402.031

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

Pain

**ICD-10 code**

G89.29

**ICD-10 code description**

Other chronic pain

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

Pain

**Timepoint**

Before the intervention and one month after the end of the intervention

**Method of measurement**

Visual analog scale

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: 31 people will be randomly assigned to this group. Two cc of lidocaine 1% (Abdi Pharmacy) will be injected in the lateral part of the knee to numb the skin of the knee. Then, the 22G needle will be inserted under ultrasound guidance from the upper and outer lateral region of the knee, and after reaching the knee joint, 5 cc of 20% dextrose solution (Obeidi Pharmacy) will be injected. The intensity of pain will be measured before and after one month after the end of the intervention using the VAS tool.

### Category

Treatment - Drugs

## 2

### Description

Control group: 31 people will be randomly assigned to this group. Two cc of lidocaine 1% (Abdi Pharmacy) will be injected in the lateral part of the knee to numb the skin of the knee. Then, the 22G needle will be inserted under ultrasound guidance from the upper and outer lateral region of the knee, and after reaching the knee joint, 4 cc of triamcinolone solution (Obeidi Pharmacy) will be injected. The intensity of pain will be measured before and after one month after the end of the intervention using the VAS tool.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Hosein Hospital

#### Full name of responsible person

Ziba Bagherian

#### Street address

Shahid Madani Ave, Imam Hossein Squ, Tehran

#### City

Tehran

#### Province

Tehran

#### Postal code

9654863529

#### Phone

+98 21 8670 5505

#### Email

Z\_bagherian@yahoo.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Behrooz Abtahi

#### Street address

Shahid Shahriari Square, Evin, Tehran

#### City

Tehran

#### Province

East Azarbaijan

#### Postal code

5165665631

#### Phone

+98 21 3335 7310

#### Email

Abtahi@hotmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Mehdi Khanbabayi Gol

#### Position

MSc in Nursing Education

#### Latest degree

Master

#### Other areas of specialty/work

Nursery

#### Street address

Imam Reza Hospital, Azadi Ave

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#### Email

Khanbabayimehdi69@gmail.com

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Mehdi Khanbabayi Gol

**Position**  
MSc in Nursing Education

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## **Person responsible for updating data**

### **Contact**

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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