Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Researvh ethics committees of cice-chancellor in research affaris 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

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Province

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9654863529

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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

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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

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Person responsible for scientific

inquiries

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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