Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effects of Intra-articular injection of dexamethasone and vitamin D compared to injection of just dexamethasone on signs of knee osteoarthritis with grade 2 and 3_ a randomized double-blind clinical trial

Protocol summary

Study aim

Evaluation of the effect of intra-articular injection of vitamin D3 with dexamethasone in the knee joint of patients with grade 2 and 3 osteoarthritis to reduce the need for analgesia, increase range of motion and reduce joint pain compared to intra-articular injection of dexamethasone alone.

Design

This is a double-blind, randomized clinical trial on 154 patients with a case and a control group with 77 patients each. Randomization will be applied through permuted balance block randomization technique(1:1 ratio) in quadruple blocks.

Settings and conduct

The study is performed on patients with bilateral osteoarthritis in the orthopedic clinic of Shahid Madani Hospital in Karaj. For double-blinding the injecting physician and the patient are both unaware of the contents of the vial and the vials of both case and control groups have the same color.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Age between 40 to 65 2. Bilateral knee osteoarthritis 3. Having score 2 and 3 of KL (Kellgren Lawrence) system radiography 4. Completion of informed consent form Exclusion criteria: 1. Presence of secondary cause for knee osteoarthritis 2. Allergic history to dexamethasone or vitamin D3 3. History of diabetes or coagulopathy 4. History or manifestation of joint infection or deformity

Intervention groups

After reviewing inclusion and exclusion criteria, 154 patients will be selected and divided into a case and a control group with 77 patients in each after completing the questionnaire of general information and WOMAC score questionnaire. In the case group, we inject 4 mg of dexamethasone with 150000 IU of vitamin D3 in each intra-articular space of the knee; and in the control group, we inject 4 mg of dexamethasone alone.

Main outcome variables

Change in osteoarthritis symptoms, the need for analgesia, the range of motion of the knee and knee pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220526054993N1**
Registration date: **2022-06-29, 1401/04/08**
Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**
Update count: **0**

Registration date

2022-06-29, 1401/04/08

Registrant information

Name
Ehsan Seif
Name of organization / entity
Alborz University of Medical Science
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-21, 1401/05/30

Expected recruitment end date

2022-11-21, 1401/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effects of Intra-articular injection of dexamethasone and vitamin D compared to injection of just dexamethasone on signs of knee osteoarthritis with grade 2 and 3_ a randomized double-blind clinical trial

Public title
Evaluation of the effect of intra-articular injection of dexamethasone and vitamin D compared to injection of dexamethasone alone on signs of knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 40 to 65 Bilateral knee osteoarthritis Having score 2 and 3 of KL system radiography Completion of informed consent form to enter the study

Exclusion criteria:
Presence of secondary cause for knee osteoarthritis Allergic history to dexamethasone or vitamin D History of diabetes or coagulopathy History or manifestation of joint infection or deformity

Age
From **40 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **154**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation of patients to case and control groups is done using "permuted balance block randomization technique" with a ratio of (1: 1). The blocks considered in this study include 4 patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
For the two-sided blindness of the study, after randomly assigning the patient to one of the two groups, one of the colleagues fills the syringe from one of the two types of vial that both have the same color. (Vitamin D and dexamethasone or dexamethasone alone). Both the physician and the patient are not informed of the contents of the syringe.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of Alborz University of Medical Science

Street address
N.528 - 120 street - Eram boulvard - Mehrshahr - Karaj

City
Karaj

Province
Alborz

Postal code
۳۱۸۵۷۴۶۹۵۷

Approval date
2022-04-16, 1401/01/27

Ethics committee reference number
IR.ABZUMS.REC.1401.018

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis with grade 2 and 3

ICD-10 code
M16.30

ICD-10 code description

Primary outcomes

1

Description
The score obtained in the WOMAC knee score to evaluate the degree of osteoarthritis

Timepoint
Before intervention and 1, 3, and 6 month after intervention

Method of measurement
WOMAC knee score

Secondary outcomes

1

Description
The amount of analgesic consumption

Timepoint
Before intervention and 1, 3, and 6 mouths after

intervention

Method of measurement

Questionnaire to assess the number of analgesics consumed per week

2

Description

Range of motion of the knee

Timepoint

Before intervention and 1, 3, and 6 mouths after intervention

Method of measurement

Clinical examination

3

Description

Joint pain

Timepoint

Before intervention and 1, 3, and 6 mouths after intervention

Method of measurement

The size of joint pain in millimeters on the scaled ruler

Intervention groups

1

Description

Intervention group: After randomization , 4 mg of dexamethasone plus one hundred and fifty thousand international units (IU) of vitamin D3 will be injected into the intra-articular space of the patient's knees separately (right and left knee). The pharmacological form of vitamin D3 which we use is Cholecalciferol from AburaihanCo.Iran .

Category

Treatment - Drugs

2

Description

Control group: After randomization, 4 mg of dexamethasone is injected separately into the intra-articular space of the knees of control patients separately (right knee and left knee). To double-blinding, the drug is injected in the same condition as the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic clinic of Shahid Madani Hospital

Full name of responsible person

Arvin Najafi

Street address

Shahid Madani Square, Mahan Boulevard, Taleghani intersection, Karaj

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Science

Full name of responsible person

Hatam Godini

Street address

Deputy of research and technology- Golshahr Street- Karaj

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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

Alborz University of Medical Science

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
Alborz University of Medical Science

Full name of responsible person
Arvin Najafi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
All data will be available after deidentification

When the data will become available and for how long
Upon rational request

To whom data/document is available
To the researchers

Under which criteria data/document could be used
For research purposes, such as meta analysis or systematic reviews

From where data/document is obtainable
From corresponding author

What processes are involved for a request to access data/document
To be an verified researcher in the field

Comments