Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of efficacy and safety of intra-articular injection of dexmedetomidine and triamcinolone in improving knee pain and function in patients with primary knee osteoarthritis

Protocol summary

Study aim
Comparison of efficacy and safety of intra-articular injection of two drugs dexmedetomidine and triamcinolone in improving knee pain and function in patients with primary knee osteoarthritis

Design
A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2-3, was conducted on 60 patients, and a simple individual randomization method was used with the tool of sealed envelopes.

Settings and conduct
This study is conducted as a double-blind randomized clinical trial in patients with osteoarthritis of the knee referred to the pain clinic of Imam Hossein hospital in 2023.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 40 years and older, knee osteoarthritis pain for more than three months, radiological findings confirming knee osteoarthritis based on the American College of Rheumatology (ACR) criteria. Exclusion criteria: patients with a lack of consent based on participation in the project, patients with a history of knee surgery, deformity and contracture of the lower limb, neuromuscular disease of the lower limb, acute lumbar pathology, injection of steroid drugs in the last two months, history of inflammatory rheumatoid arthritis, infection, Diabetes, pregnancy, breastfeeding, BMI<35, patients who are candidates for knee surgery, presence of knee deviation (varus or valgus more than five degrees) which was confirmed by three joint view, presence of radiocular knee pain, use of anticoagulant drugs, arthritis after Trauma, history of intra-articular injection in the past 12 months, allergy to any of the drugs, severe osteoarthritis with grade more than III, drug and alcohol abuse.

Intervention groups
Intervention group: injection of dexmedetomidine 1 microgram per kilogram + 2 ml of 2% lidocaine inside the knee joint. Control group: injection of 40 mg of triamcinolone inside the knee joint

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130518013364N11**
Registration date: **2023-09-27, 1402/07/05**
Registration timing: **prospective**

Last update: **2023-09-27, 1402/07/05**
Update count: **0**

Registration date
2023-09-27, 1402/07/05

Registrant information

Name
Mehrdad Taheri

Name of organization / entity
Shahid Beheshti 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
2023-10-02, 1402/07/10

Expected recruitment end date

2024-02-09, 1402/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of intra-articular injection of dexmedetomidine and triamcinolone in improving knee pain and function in patients with primary knee osteoarthritis

Public title

Comparison of intra-articular injection of dexmedetomidine and triamcinolone in improving knee pain and function in patients with primary knee osteoarthritis.

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 40 years Presence of knee pain for more than 3 months Radiological findings confirming knee osteoarthritis based on American College of Rheumatology (ACR) criteria

Exclusion criteria:

Unwillingness to participate in the study Patients with a history of knee surgery Patients with lower limb deformity and contracture Patients with lower limb neuromuscular disease Patients with acute lumbar pathology Injection of steroid drugs during the last two months History of inflammatory rheumatoid arthritis History of recent infection in the knee Diabetes Pregnancy Breastfeeding BMI> 35 Candidate patients for knee surgery The presence of knee deviation (Varus or valgus more than five degrees) which was confirmed by three joint view The presence of radicular pain Taking anticoagulants Arthritis after trauma History of intra-articular injection of the knee during the last 12 months Allergy to any of the drugs used Chronic systemic disease Psychiatric illness Severe osteoarthritis with grade more than III Hepatitis Cytomegalovirus infection Having syphilis Having osteomyelitis Drug and alcohol abuse Having AIDS

Age

From **40 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization is done with sealed envelope tools in such a way that the letters A and B are inserted in the envelopes and patients are asked to select an envelope that the intervention group A and the group B will be as control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient herself and the doctor who evaluates the outcome in patients do not know the patient group (intervention group or control group)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2023-07-30, 1402/05/08

Ethics committee reference number

IR.SBMU.RETECH.REC.1402.267

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain

Timepoint

At the beginning of the study (before the start of the

intervention) and one and three months after

Method of measurement

Visual analog scale

2

Description

The total score of the KOOS questionnaire

Timepoint

At the beginning of the study (before the start of the intervention) and one and three months after

Method of measurement

Based on asking the patient and scoring each of the items

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of dexmedetomidine 1 microgram per kilogram + 2 ml lidocaine 2%, which is performed under ultrasound guidance with a 27-gauge needle inside the knee joint. The injection is done in one session.

Category

Treatment - Other

2

Description

Control group: Injection of one milliliter (40 mg) of triamcinolone + 2 ml of lidocaine 2%. The injection method is similar to the intervention group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital’s pain clinic

Full name of responsible person

Mehrdad Taheri

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Shahid Madani street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarqi

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mehrdad Taheri

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Latest degree
Subspecialist
Other areas of specialty/work
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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
Not applicable
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
No - There is not a plan to make this available
Data Dictionary
Not applicable