

# 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 radioculur 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7756 7840

##### Email address

m.taheri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-02, 1402/07/10

##### Expected recruitment end date

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <div>2024-02-09, 1402/11/20</div> <div>Actual recruitment start date</div> <div>empty</div> <div>Actual recruitment end date</div> <div>empty</div> <div>Trial completion date</div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <div>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.</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <div>Scientific title</div> <div>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</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <div>Blinding (investigator's opinion)</div> <div>Double blinded</div> <div>Blinding description</div> <div>The patient herself and the doctor who evaluates the outcome in patients do not know the patient group (intervention group or control group)</div> <div>Placebo</div> <div>Not used</div> <div>Assignment</div> <div>Parallel</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <div>Public title</div> <div>Comparison of intra-articular injection of dexmedetomidine and triamcinolone in improving knee pain and function in patients with primary knee osteoarthritis.</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <div>Other design features</div> <div>Secondary Ids</div> <div>empty</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <div>Purpose</div> <div>Health service research</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <div>Ethics committees</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <div>Inclusion/Exclusion criteria</div> <div>Inclusion criteria:</div> <div>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</div> <div>Exclusion criteria:</div> <div>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&gt; 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</div> | <div>1</div> <div>Ethics committee</div> <div>Name of ethics committee</div> <div>Ethics committee of Shahid Beheshti University of Medical Sciences</div> <div>Street address</div> <div>Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway, Shahid Beheshti University Of Medical Sciences</div> <div>City</div> <div>Tehran</div> <div>Province</div> <div>Tehran</div> <div>Postal code</div> <div>1617763141</div> <div>Approval date</div> <div>2023-07-30, 1402/05/08</div> <div>Ethics committee reference number</div> <div>IR.SBMU.RETECH.REC.1402.267</div> <div>Health conditions studied</div> <div>1</div> <div>Description of health condition studied</div> <div>Osteoarthritis of knee</div> <div>ICD-10 code</div> <div>M17.0</div> <div>ICD-10 code description</div> <div>Bilateral primary osteoarthritis of knee</div> |
| <div>Age</div> <div>From 40 years old</div> <div>Gender</div> <div>Both</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <div>Phase</div> <div>2-3</div> <div>Groups that have been masked</div> <div> <ul style="list-style-type: none"> <li>Participant</li> <li>Outcome assessor</li> </ul> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <div>Primary outcomes</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <div>Sample size</div> <div>Target sample size: 60</div> <div>Randomization (investigator's opinion)</div> <div>Randomized</div> <div>Randomization description</div> <div>A simple randomization is done with sealed envelope</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <div>1</div> <div>Description</div> <div>Pain</div> <div>Timepoint</div> <div>At the beginning of the study (before the start of the</div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

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

##### Street address

Shahid Madani street

##### City

Tehran

##### Province

Tehran

##### Postal code

1617763141

##### Phone

+98 21 7343 0000

##### Email

m.taheri@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarqi

##### Street address

Shahid Abbas Arabi Street, Yemen Street, Shahid Chamran highway

##### City

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##### Province

Tehran

##### Postal code

1985717434

##### Phone

+98 21 2243 9951

##### Email

mpd@sbmu.ac.ir

##### Web page address

<https://research.sbmu.ac.ir>

#### 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

##### Street address

Shahid Madani street, Imam Hossein Hospital

##### City

Tehran

##### Province

Tehran

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1617763141  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Associate professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
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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