# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Jun 2026

## Evaluation the effect of local Dexmedetomidine injection on post operative pain in total knee arthroplasty surgery

## Protocol summary

**Study aim**

Various drugs are administered intra-articularly to provide postoperative analgesia after total knee arthroplasty surgery. The purpose of this study was to assess the analgesic effects of intra-articular injection of a Dexmedetomidine following total knee arthroplasty.

**Design**

24 patients scheduled for total knee arthroplasty surgery under spinal anaesthesia, will be randomly devided into two groups. Patients will be divided into two groups by random number table. Intervention group will be received 1µg/kg dexmedetomidine and isotonic saline and control group received 25ml isotonic saline.

**Settings and conduct**

This double-blind randomized study will be conducted in the (C) operating room of Imam Khomeini Hospital in Orumiyeh.The syringes used are 5 ml and the surgeon will not know its content. Syringes containing drug and placebo in the two groups A and B will be prepared and labeled by someone else. After placing in the box randomly, a syringe with each sticker will be removed from the box and injected into the patient which was without the knowledge of the researcher and the patient and after completing the entire questionnaire, the researcher will be informed.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: patient with class I to III America society of Anesthesiologists؛ surgery with spinal anesthesia Exclusion criteria: Cardiovascular disease؛ Neuropathic Disease؛ Previous surgery on the knee؛ Congenital deformity in the treated organ؛ Sensitivity to drugs used in the study؛ Arthroplasty for revision

**Intervention groups**

The purpose of this study was to assess the analgesic effects of intra-articular injection of a dexmedetomidine following total knee arthroplasty.Intervention group will be received 1µg/kg dexmedetomidine and isotonic saline and control group received 25ml isotonic saline.

**Main outcome variables**

Average postoperative pain score

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160430027677N7**
Registration date: **2018-01-05, 1396/10/15**
Registration timing: **retrospective**

Last update: **2018-01-05, 1396/10/15**
Update count: **0**

**Registration date**

2018-01-05, 1396/10/15

**Registrant information**

**Name**
Shahryar Sane
**Name of organization / entity**
Urmia University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 44 3223 4897
**Email address**
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2017-05-22, 1396/03/01

**Expected recruitment end date**

2017-12-22, 1396/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Evaluation the effect of local Dexmedetomidine injection on post operative pain in total knee arthroplasty surgery

**Public title**
Clinical trial the effect of local Dexmedetomidine injection on post operative pain in patient with total knee arthroplasty surgery

**Purpose**
Prevention

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patient with class I to III America society of Anesthesiologists; surgery with spinal anesthesia

**Exclusion criteria:**
Cardiovascular disease; Neuropathic Disease; Congenital deformity in the treated organ; Sensitivity to drugs used in the study; Arthroplasty for revision

**Age**
No age limit

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **12**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients will be divided into two groups by random number table.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The syringes used are 5 ml and the surgeon will not know its content. Syringes containing drug and placebo in the two groups A and B will be prepared and labeled by someone else. After placing in the box randomly, a syringe with each sticker will be removed from the box and injected into the patient which was without the knowledge of the researcher and the patient and after completing the entire questionnaire, the researcher will be informed

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics commitee of Urmia University of Medical Sciences

**Street address**
Emergent Street, Ershad Avenue

**City**
Urmia

**Province**
West Azarbaijan

**Postal code**
5714783734

**Approval date**
2017-04-19, 1396/01/30

**Ethics committee reference number**
ir.umsu.rec.1396.6

## Health conditions studied

### 1

**Description of health condition studied**
Post operative pain

**ICD-10 code**
G90.529

**ICD-10 code description**
Complex regional pain syndrome I of unspecified lower limb

## Primary outcomes

### 1

**Description**
Postoperative pain

**Timepoint**
In recovery, 6 and 12 hours after surgery

**Method of measurement**
Visual Analogue Scale

## Secondary outcomes

### 1

**Description**
The average need for an analgesic drug to control pain

**Timepoint**
In 12 hours after surgery

**Method of measurement**
milligram

### 2

**Description**
The first time to apply for post-operative pain control

**Timepoint**
In 12 hours after surgery

**Method of measurement**
hour

**3**

**Description**
Postoperative bleeding is to 12 hours
**Timepoint**
In 12 hours after surgery
**Method of measurement**
Based on the amount of blood in the Hamovak donor, it is determined in 24 hours and the amount of hemoglobin in the postoperative patients.

**4**

**Description**
Sleep disorder after surgery
**Timepoint**
In 24hours after surgery
**Method of measurement**
Visual Analogue Scale

## Intervention groups

**1**

**Description**
Intervention group: The study group will be received dexmedetomidine 1 micg/kg of body weight for dexamethasone
**Category**
Treatment - Drugs

**2**

**Description**
Control group: will be received 25 milliliter isotonic saline
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Emam Khomeini Hospital, C operating room
**Full name of responsible person**
Shahryar Sane ,Associate Professor, Anesthesiologist
**Street address**
Modarres Avenue, Ershad Avenue
**City**
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**Postal code**
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**Email**
sanesh@umsu.ac.ir

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Oroumia University of Medical Sciences
**Full name of responsible person**
Shahryar Sane
**Street address**
Emam Khomeini Hospital, Modarres Avenue, Ershad Avenue
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**Fax**
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**Email**
sanesh@umsu.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Oroumia 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**
Oroumia University of Medical Sciences
**Full name of responsible person**
Shahryar Sane
**Position**
Associate professor,
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
At the beginning of the plan, no data dissemination was approved.
**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