

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 divided 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 American 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

sane.sh@umsu.ac.ir

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 committee 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

uemia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

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

City

uemia

Province

West Azarbaijan

Postal code

5715781351

Phone

+98 44 3346 9931

Fax

+98 44 3346 8967

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

Street address

Emergrnt Street, Resalat Avenue

City

uemia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44332234897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

Person responsible for scientific 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
Street address
Emergrnt Street, Resalat Avenue
City
uemia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44332234897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

Person responsible for updating data

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
Street address
Emergent Street, Ershad Avenue
City
uemia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44332234897
Fax
+98 44 3346 8967
Email
sanesh@umsu.ac.ir

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