Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

The Effect of intra-articular injection of Dexmedetomidine on pain after knee arthroscopic surgery

Protocol summary

Study aim
This study investigated the efficacy of intra-articular injection of Dexmedetomidine in the evaluation of postoperative analgesia in patients undergoing knee arthroscopy.

Design
The clinical trial included a control group with a parallel, double-blind, randomized block design.The sample size is 70 patients which will be divided into two groups.

Settings and conduct
This study will be performed on patients who are candidates for knee arthroscopic surgery and go to Susangard Oil Martyrs Hospital in Iran. After proper cardiopulmonary monitoring and proper hydration, the patient undergoes spinal anesthesia.At the end of the arthroscopy 15 minutes before the tourniquet was opened, in one group of patients, 2µg / kg dexmedetomidine (Elixir, Iran) with normal saline 0.9% increased to 20 ml and in another group only 20 ml of normal saline 0.9% using by injection of Quincke (G-25) sterile method to the knee intra-articular space by a surgeon .The suture site will then be sutured.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients with ASA class I and II and patients aged 18 to 60 years;Exclusion criteria are: renal failure, liver failure, valvular and ischemic heart disease (indicated by patient history, physical examination and ECG and echocardiography), hypertension, diabetes, consumers opiate substances, NSAIDs and analgesics 24 hours before surgery, history of infection and malignancy, history of coagulopathy and drug allergy

Intervention groups
Intervention group: ،The effectiveness of intra-articular injection of dexmedetomidine in the amount of pain after knee arthroscopic surgery will be examined. Control group:The effectiveness of intramuscular injection of dexmedetomidine in the amount of pain after knee arthroscopy will be investigated.

Main outcome variables
Postoperative pain; Time of first analgesia; Total analgesia received.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200205046390N1**
Registration date: **2020-06-07, 1399/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-07, 1399/03/18**
Update count: **0**

Registration date
2020-06-07, 1399/03/18

Registrant information

Name
Yasaman Esfahanian

Name of organization / entity

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Iran (Islamic Republic of)

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+98 61 3390 3016

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-20, 1398/10/30

Expected recruitment end date
2020-09-21, 1399/06/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of intra-articular injection of Dexmedetomidine on pain after knee arthroscopic surgery

Public title

Effect of Dexmedetomidine on knee arthroscopic surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are candidates for knee arthroscopic surgery Patients with ASA class I and II

Exclusion criteria:

Renal failure Liver failure Valve and Ischemic Heart disease Hypertension Diabetes Drug users Consumer analgesics within 24 hours before surgery History of infection and malignancy History of Coagulopathy Drug reaction

Age

From **18 years** old to **60 years** old

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are randomly divided into two groups according to the random block permutation method. For example, for blocks of four, we have 6 blocks of AABB, ABAB, BABA, BBAA, BAAB and ABBA which must be n / 4th of these blocks as By placing the sample, the randomization unit is individualized.Random tool is statistical software. Randomization was obtained from www.sealedenevelope.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are not aware of medication or placebo, despite knowing they were enrolled. The surgeon is also unaware of the contents of the injection in this study because the drug is made available to the outcome assessor. Questionnaire collectors are also unaware of the group of patients receiving the drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No. 87, Phase 2, West 8th Street, Kianpars

City

Ahwaz

Province

Khouzestan

Postal code

6155846600

Approval date

2020-01-17, 1398/10/27

Ethics committee reference number

IR.AJUMS.REC.1398.771

Health conditions studied

1

Description of health condition studied

The effect of Dexmedetomidine on analgesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain

Timepoint

Postoperative pain severity was assessed at 1, 2, 4, 8, 16, 24 hour after injection

Method of measurement

Visual Analogue Scale criterion (from 0 painless to 10 most painful)

2

Description

Time to receive the first analgesic

Timepoint

During the 24 hours after the operation

Method of measurement

Minutes

3

Description

Total analgesics consumption

Timepoint

During the 24 hours after the operation

Method of measurement
milligram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group of patients, 2 mg / kg dexmedetomidine (Elixir, Iran) together with normal saline 0.9% increased the volume to 20 ml, then using Needle Spinal No. 25, Quincke type is injected into the intra-articular space of the knee by sterile method.Then we will sew the place.
Category
Treatment - Drugs

2

Description
Control group:normal saline 0.9% increased the volume to 20 ml, then using Needle Spinal No. 25, Quincke type is injected into the intra-articular space of the knee by sterile method.Then we will sew the place.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Azadegan Plain Martyrs Hospital
Full name of responsible person
Yasaman Esfahanian
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ground floor, Vice-Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences,University City
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6135715794
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itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Yasaman Esfahanian
Position
Resident
Latest degree
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Person responsible for scientific

inquiries

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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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual data are shared about the main outcome of the study, including the degree of analgesia and hemodynamic information of patients.
When the data will become available and for how long
Start of access period 12 months after printing results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
In order to use the data of this study in other research and to raise awareness in the field of performance
From where data/document is obtainable
Visit Esfahanian.Y@ajums.ac.ir by email
What processes are involved for a request to access data/document
The information will be sent one week after receiving the email
Comments