# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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**

**Country**

Iran (Islamic Republic of)

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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**
Daneshjoo Street
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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
**City**
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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**
Medical doctor
**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)**
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**