

# Comparison of dexmedetomidine and ketamine on pain after total knee arthroplasty

<b>Submission date</b> 13/06/2025	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/06/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/06/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study looked at two medications, dexmedetomidine and ketamine, to find out which one works better in reducing pain and the need for strong painkillers after knee replacement surgery (total knee arthroplasty). Both drugs are often used during surgery as part of a pain relief strategy called multimodal analgesia.

### Who can participate?

Adults aged 18 years or over, who were scheduled for elective single-knee replacement surgery under spinal anesthesia and were physically fit

### What does the study involve?

Participants were randomly placed into two groups. One group received dexmedetomidine, the other received ketamine, both during surgery. Everyone also received a femoral nerve block and standard spinal anesthesia. Pain levels, use of painkillers, vital signs, and satisfaction were monitored for 24 hours after surgery.

### What are the possible benefits and risks of participating?

There may be better pain control and a lower need for opioids. No serious side effects were observed, and there were no cases of low blood pressure or slow heart rate. All patients reported high satisfaction.

### Where is the study run from?

Hatay Mustafa Kemal University (Turkey)

### When is the study starting and how long is it expected to run for?

June 2023 to December 2024

### Who is funding the study?

Hatay Mustafa Kemal University (Turkey)

### Who is the main contact?

Dr Senem Urfalı, [senemurfali@gmail.com](mailto:senemurfali@gmail.com)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Senem Urfalı

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Comparing the effects of intraoperative dexmedetomidine and ketamine on postoperative pain in total knee arthroplasty: a randomized trial

### Acronym

DK-TKA

### Study objectives

It was hypothesized that intraoperative dexmedetomidine infusion would provide better postoperative pain control and reduce opioid consumption compared to ketamine in patients undergoing total knee arthroplasty.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 21/06/2023, Hatay Mustafa Kemal University Clinical Research Ethics Committee (Tayfur Sökmen Kampüsü Alahan-Antakya/HATAY, Hatay, 31060, Türkiye; +90 (0)(326) 221 33 17 - 18 - 19; rektorlukyaziisleri@mku.edu.tr), ref: 02

## **Study design**

Single-centre double-blinded prospective randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Total knee arthroplasty

## **Interventions**

Patients were randomly allocated into two groups (1:1 ratio) using a computer-generated randomisation list created by an independent biostatistician before patient enrolment. Block randomisation was not used. Allocation was concealed, and both patients and outcome assessors were blinded to group assignments.

Patients were randomly assigned to receive either intraoperative dexmedetomidine infusion (1 µg/kg over 10 minutes followed by 0.5 µg/kg/h) or ketamine infusion (0.1 mg/kg/h without a loading dose) under spinal anesthesia.

## **Intervention Type**

Drug

## **Phase**

Not Applicable

## **Drug/device/biological/vaccine name(s)**

Dexmedetomidine, ketamine

## **Primary outcome(s)**

Total opioid consumption (in milligrams of tramadol) is measured using data obtained from the intravenous PCA device at 24 hours postoperatively.

## **Key secondary outcome(s)**

1. Pain intensity is measured using the Visual Analogue Scale (VAS) (0 = no pain, 10 = worst pain) in both sitting and supine positions at 0, 4, 8, 12, 18, and 24 hours postoperatively
2. Need for rescue analgesia is determined based on VAS  $\geq 4$ , and the administration of IV meperidine (0.3 mg/kg) is recorded during the first 24 hours
3. Hemodynamic parameters including heart rate, systolic, diastolic, and mean arterial pressure are measured using noninvasive monitoring at 0, 4, 8, 12, 18, and 24 hours postoperatively
4. Ambulation time (in hours) is recorded based on the time to first mobilization after surgery
5. Side effects including postoperative nausea and vomiting, hypotension, and bradycardia are documented based on clinical observation and medication use within the first 24 hours
6. Patient satisfaction is measured using a four-point scale (0 = poor, 1 = moderate, 2 = good, 3 = excellent) at 24 hours postoperatively

**Completion date**

31/12/2024

## Eligibility

**Key inclusion criteria**

1. Adult patients aged  $\geq 18$  years
2. Scheduled for elective unilateral primary total knee arthroplasty under spinal anesthesia
3. American Society of Anesthesiologists (ASA) physical status I–III
4. Provided written informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

110 years

**Sex**

All

**Total final enrolment**

104

**Key exclusion criteria**

1. Body mass index (BMI)  $>35$  kg/m<sup>2</sup>
2. Uncontrolled hypertension
3. Renal or hepatic disease
4. Mental, psychiatric or neuromuscular disorders
5. Known allergies or contraindications to dexmedetomidine, ketamine, or local anesthetics
6. Contraindications to spinal anesthesia
7. Refusal to participate in the study

**Date of first enrolment**

01/07/2023

**Date of final enrolment**

31/12/2024

## Locations

## Countries of recruitment

Türkiye

## Study participating centre

**Hatay Mustafa Kemal University, Tayfur Ata Sökmen Faculty of Medicine**

Tayfur Sökmen Kampüsü (31060) Alahan-Antakya

Hatay

Türkiye

31060

## Sponsor information

### Organisation

Hatay Mustafa Kemal University

## Funder(s)

### Funder type

University/education

### Funder Name

Hatay Mustafa Kemal University

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from the corresponding author (please contact Dr Senem Urfalı via [senemurfali@gmail.com](mailto:senemurfali@gmail.com)).

The data include anonymised individual participant data (IPD) related to demographics, intervention details, opioid consumption, VAS scores, and hemodynamic parameters. Data will become available after publication of the study results and will be accessible for a period of 5 years. Access will be granted for academic purposes following approval of a written proposal. Participant consent for data sharing was obtained as part of the informed consent process. All data will be anonymised to protect patient confidentiality and comply with ethical guidelines.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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