# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Comparison of Pre-induction versus Post-induction Dexmedetomidine Administration on Intraoperative Fentanyl and Isoflurane Consumption in Patients Undergoing Laparoscopic Cholecystectomy: A Double-Blind Randomized Clinical Trial

## Protocol summary

**Study aim**

To compare the effects of dexmedetomidine administration before versus after induction of anesthesia on intraoperative fentanyl and isoflurane consumption, hemodynamic responses, and postoperative recovery outcomes in patients undergoing laparoscopic cholecystectomy

**Design**

A randomized, double-blind, parallel-group, placebo-controlled clinical trial with a 1:1 allocation ratio.

**Settings and conduct**

This study will be conducted at Loghman Hakim Hospital, Tehran, Iran, in eligible patients undergoing elective laparoscopic cholecystectomy. After screening for eligibility and obtaining written informed consent, participants will be randomly assigned to two groups. Anesthetic interventions will be performed according to the study protocol, and intraoperative data and postoperative outcomes will be recorded and compared.

**Participants/Inclusion and exclusion criteria**

Adults aged 18–65 years, ASA I–II, undergoing elective laparoscopic cholecystectomy under general anesthesia. Exclusion criteria: dexmedetomidine allergy, significant bradycardia or conduction disorders, major cardiovascular disease, uncontrolled hypertension, severe hepatic impairment, regular opioid use, alpha-2 agonist use within 7 days, pregnancy, or breastfeeding

**Intervention groups**

Group A: Dexmedetomidine 1 µg/kg infused over 10 minutes before anesthesia induction, followed by 0.5 µg/kg/h maintenance infusion Group B: Placebo before induction, followed by dexmedetomidine at the same loading and maintenance doses after induction

**Main outcome variables**

Total intraoperative fentanyl consumption (µg/ kg) Total intraoperative isoflurane consumption (mL)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20210415050983N16**
Registration date: **2026-11-19, 1405/08/28**
Registration timing: **prospective**

Last update: **2026-11-19, 1405/08/28**
Update count: **0**

**Registration date**

2026-11-19, 1405/08/28

**Registrant information**

**Name**

Sogol Asgari

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-11-22, 1405/09/01

**Expected recruitment end date**

2026-12-22, 1405/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Comparison of Pre-induction versus Post-induction Dexmedetomidine Administration on Intraoperative Fentanyl and Isoflurane Consumption in Patients Undergoing Laparoscopic Cholecystectomy: A Double-Blind Randomized Clinical Trial

**Public title**
Comparison of Pre-induction versus Post-induction Dexmedetomidine Administration on Fentanyl and Isoflurane Consumption in Patients Undergoing Laparoscopic Cholecystectomy: A Randomized Clinical Trial

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
ASA physical status I or II Scheduled for elective laparoscopic cholecystectomy under general anesthesia. Willingness to participate and provision of written informed consent

**Exclusion criteria:**
Known hypersensitivity to dexmedetomidine or study medications. Significant bradycardia, advanced atrioventricular block, or clinically significant cardiac conduction disorders. Significant cardiovascular disease or uncontrolled hypertension Severe hepatic impairment. Regular opioid use or opioid dependence. Use of dexmedetomidine or other alpha-2 agonists within the previous 7 days. Pregnancy or breastfeeding.

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **78**

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

**Randomization description**
Eligible patients will be randomly allocated in a 1:1 ratio to the two study groups using a computer-generated random sequence. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes.

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

**Blinding description**
The study will be conducted in a double-blind manner. Study medications will be prepared by an independent anesthesiologist in identical syringes or infusion containers with identical labeling. Patients and outcome assessors will remain blinded to group allocation. The anesthesiologist responsible for drug preparation will not participate in outcome assessment.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Vice for Research and Technology, Shahid Beheshti University of Medical Sciences

**Street address**
Velenjak, Yemen Street, Shahid Shahriari Square.

**City**
Tehran

**Province**
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**Postal code**
1985717443

**Approval date**
2026-11-04, 1405/08/13

**Ethics committee reference number**
IR.SBMU.MSP.REC.1405.572

## Health conditions studied

### 1

**Description of health condition studied**
Cholelithiasis and cholecystitis

**ICD-10 code**
K80.1

**ICD-10 code description**
Calculus of gallbladder with other cholecystitis

## Primary outcomes

### 1

**Description**
Total intraoperative fentanyl consumption (µg/kg)

**Timepoint**
At the end of surgery and anesthesia; total fentanyl consumption will be recorded.

**Method of measurement**
Total intraoperative fentanyl consumption will be calculated by summing all administered doses and dividing by body weight (µg/kg).

## Secondary outcomes

**1**

**Description**
total intraoperative isoflurane consumption (mL) as a secondary outcome, and compared between the two groups.
**Timepoint**
At the end of surgery and anesthesia; total isoflurane consumption will be recorded.
**Method of measurement**
Total isoflurane consumption will be recorded in milliliters (mL)

## Intervention groups

**1**

**Description**
Group A : Dexmedetomidine 1 µg/kg will be administered intravenously over 10 minutes before anesthesia induction, followed by a maintenance infusion of 0.5 µg/kg/h. After induction, an equivalent-volume placebo infusion will be administered.
**Category**
Treatment - Drugs

**2**

**Description**
Group B : An equivalent-volume placebo will be administered over 10 minutes before anesthesia induction. Following induction, dexmedetomidine 1 µg/kg will be administered intravenously over 10 minutes, followed by a maintenance infusion of 0.5 µg/kg/h.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Loghman Hakim Hospital, Tehran, Iran.
**Full name of responsible person**
Masood Nashibi
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
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**Full name of responsible person**
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shahid Beheshti 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**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Sogol Asgari
**Position**
Assistant Professor
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Subspecialist
**Other areas of specialty/work**
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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)**
Undecided - It is not yet known if there will be a plan to make this available
**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