# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Comparing the effects of intravenous dexmedetomidine infusion with intravenous dexamethasone in providing analgesia and reducing nausea and vomiting after laparoscopic cholecystectomy

### Protocol summary

**Study aim**

Comparing the effects of intravenous dexmedetomidine infusion with intravenous dexamethasone in providing analgesia and reducing nausea and vomiting after laparoscopic cholecystectomy

**Design**

A triple-blind clinical trial on 165 male and female patients aged 18-60 years undergoing laparoscopic cholecystectomy with the aim of reducing pain, nausea and vomiting. Randomized sample collection with 3 parallel groups, phase 3, patients receiving placebo, dexmedetomidine and dexamethasone.

**Settings and conduct**

The study is a triple-blind randomized clinical trial and includes patients with a diagnosis of laparoscopic cholecystectomy who will be evaluated in 1404 at Al-Zahra Hospital in Isfahan. The participant, clinical caregiver, researcher, and data analyst in this study are blinded, and only the outcome analyst is awake.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patient consent to enter the study/ Patient must be a candidate for laparoscopic cholecystectomy/ American Society of Anesthesiologists (ASA) Class II-I/ No prior history of chemotherapy/ Age 18 to 60 years/ Maximum duration of operation 150 minutes
Inclusion criteria: Preoperative steroid use/ Allergy to dexamethasone or dexmedetomidine/ Pregnancy

**Intervention groups**

The group that received 0.5-1 µg of dexmedetomidine as a bolus over ten minutes and a dose of 0.7-0.2 µg/kg/h infusion. The group that received 4 mg/2 ml of dexamethasone in a single dose and 0.1 mg/kg of normal saline in a final volume of 20 cc. The group that received placebo (normal saline).

**Main outcome variables**

Nausea, pain, vomiting, systolic and diastolic blood pressure, heart rate, o2sat

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20160307026950N81**
Registration date: **2026-06-19, 1405/03/29**
Registration timing: **prospective**

Last update: **2026-06-19, 1405/03/29**
Update count: **0**

**Registration date**

2026-06-19, 1405/03/29

**Registrant information**

**Name**

Behzad Nazemroaya

**Name of organization / entity**

Isfahan University of Medical Sciences

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**Recruitment status**

**recruiting**

**Funding source**

**Expected recruitment start date**

2026-06-22, 1405/04/01

**Expected recruitment end date**

2027-08-11, 1406/05/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Comparing the effects of intravenous dexmedetomidine infusion with intravenous dexamethasone in providing analgesia and reducing nausea and vomiting after laparoscopic cholecystectomy

**Public title**
The effect of intravenous dexmedetomidine with intravenous dexamethasone in providing analgesia and reducing nausea and vomiting after laparoscopic cholecystectomy.

**Purpose**
Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patient consent to enter the study The patient is a candidate for laparoscopic cholecystectomy. American Society of Anesthesiologists (ASA) Class II-I No prior history of chemotherapy Age 18 to 60 years Maximum operation time 150 minutes

**Exclusion criteria:**
Taking steroids before surgery Allergy to dexamethasone or dexmedetomidine being pregnant

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

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **165**

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

**Randomization description**
Three drugs are named A, B, and C, and only the third person who gives the drug to the patient knows which drug has which letter, and decoding is done at the end of the study. People are written from top to bottom based on the national code, and based on a random method, if the number 1 is determined, the first group, that is, three people, enters the ABC group, and the first person A, the second person B, and the third person C. If the random number 2 comes, the second group in the same way, and if the random number 3 comes, the third group, if the random number 4 comes, group 4, if the random number 5 comes, group 5, and if the random number 6 comes, group 6. If the random numbers 7, 8, and 9 come, it is repeated until one of the random numbers comes up. We have 55 random blocks of three. For example, if two patients are candidates for surgery today, we assume a third patient and form a block and specify the block. If the third patient comes in the future, his block is already specified and he will receive the desired drug.

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

**Blinding description**
-The participants are the same patients who have undergone abdominal cholecystectomy surgery and are blinded in this study because the study was explained to them before consent was obtained, but they are not aware of the coding of the groups and the grouping. -The nursing and operating room staff are also blinded as clinical care because they are not aware of the grouping. -The researcher is also blinded in this study because he does not personally perform the grouping and drug injection. -The professor, statistical consultant and student (researcher) are also blinded as data analysts in this study because they only analyze and interpret the collected information. -The only group that is awake is the nursing staff and the drug injectors who collect the data and are aware of the coding of the groups and the grouping and the intervention that is performed for each patient.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**

**Name of ethics committee**
Research Ethics Committee of Alzahra Research Centers , Isfahan University of Medical Sciences

**Street address**
Hezar jerib

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**Postal code**
8174673461

**Approval date**
2026-01-20, 1404/10/30

**Ethics committee reference number**
IR.ARI.MUI.REC.1404.290

## Health conditions studied

**1**

**Description of health condition studied**
laparoscopic cholecystectomy

**ICD-10 code**
K80

**ICD-10 code description**
Cholelithiasis

## Primary outcomes

**1**

**Description**

Nausea

**Timepoint**

From patient recovery until 4 hours after surgery, every 30 minutes in 3 groups

**Method of measurement**

Ask the patient

**2**

**Description**

Vomiting

**Timepoint**

From patient recovery until 4 hours after surgery, every 30 minutes in 3 groups

**Method of measurement**

Ask the patient

**3**

**Description**

pain

**Timepoint**

From patient recovery until 4 hours after surgery, every 30 minutes in 3 groups

**Method of measurement**

VAS score system

**4**

**Description**

Systolic blood pressure

**Timepoint**

During the procedure after receiving the medication, every 15 minutes until the end of the surgery.

**Method of measurement**

Non invasive blood pressure measurement

**5**

**Description**

Diastolic blood pressure

**Timepoint**

During the procedure after receiving the medication, every 15 minutes until the end of the surgery.

**Method of measurement**

Non invasive blood pressure measurement

**6**

**Description**

Heart rate

**Timepoint**

During the procedure after receiving the medication, every 15 minutes until the end of the surgery.

**Method of measurement**

ECG Monitoring

**7**

**Description**

Blood oxygen saturation

**Timepoint**

During the procedure after receiving the medication, every 15 minutes until the end of the surgery.

**Method of measurement**

Pulse oximeter

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group:The group that received 0.5-1 µg dexmedetomidine as a bolus over ten minutes and a dose of 0.2-0.7 µg/kg/h infusion

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Group receiving 4mg/2ml dexamethasone single dose and 0.1mg/kg normal saline to a final volume of 20cc

**Category**

Treatment - Drugs

**3**

**Description**

Control group: The group receiving placebo (normal saline).

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Isfahan Alzahra Hospital

**Full name of responsible person**

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## Sponsors / Funding sources

**1**

**Sponsor**

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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**
Esfahan 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**

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Esfahan University of Medical Sciences

**Full name of responsible person**
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A Level or less

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General Practitioner

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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