

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### A comparative study of the effect of general anesthesia , general anesthesia/ epidural analgesia on pain intensity and common complications after laparoscopic cholecystectomy

#### Protocol summary

##### Study aim

Determination and comparison of pain intensity and common complications after laparoscopic cholecystectomy surgery in patients under general anesthesia with patients receiving general anesthesia with epidural anesthesia.

##### Design

Several 100 patients, candidates for laparoscopic cholecystectomy surgery and meeting the study entry criteria, will be included in the easy sampling method with random allocation. After obtaining written informed consent, the participants are divided into two intervention and control groups, each group containing 50 participants.

##### Settings and conduct

The study is conducted by the surgical team of Shahid Jalil Hospital, Yasouj University of Medical Sciences. In this study, the evaluator and data analyzer were blinded. Epidural anesthesia using the allowed amount of marcaine 0.05% and lidocaine 2% before the induction of general anesthesia in the form of injection, a single shot epidural is performed for the intervention group. To evaluate common complaints and the level of pain intensity, use the McGill questionnaire and self-administered questionnaire. The questionnaires will be completed by a blinded evaluator, in the first stage at the time of patient admission and in the second stage in the recovery room after surgery and when the patient is awake at zero, 4, 6, 12, and 24 hours.

##### Participants/Inclusion and exclusion criteria

The patient is a candidate for laparoscopic cholecystectomy surgery and has no underlying diseases related to surgery or a history of sensitivity to anesthetics or local anesthesia.

##### Intervention groups

The intervention group will receive general anesthesia with epidural analgesia, and the control group will only

be under general anesthesia.

##### Main outcome variables

-Severity of pain -Type of anesthesia -Cardiopulmonary complications -Nausea and vomiting -Right shoulder pain  
- Abdominal discomfort - Urinary retention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200207046408N3**

Registration date: **2024-02-20, 1402/12/01**

Registration timing: **prospective**

Last update: **2024-02-20, 1402/12/01**

Update count: **0**

##### Registration date

2024-02-20, 1402/12/01

##### Registrant information

##### Name

Reza Hosseinpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 1813

##### Email address

reza.hosseinpour@yums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-03, 1403/01/15

##### Expected recruitment end date

2024-05-20, 1403/02/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparative study of the effect of general anesthesia , general anesthesia/ epidural analgesia on pain intensity and common complications after laparoscopic cholecystectomy

**Public title**

Investigating the effect of epidural analgesia with general anesthesia on pain intensity and common complications after laparoscopic cholecystectomy compared to general anesthesia

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

A patient who is a candidate for laparoscopic cholecystectomy surgery (with symptomatic gallstones without complications, with ASA grade 1 or 2) Willingness to participate in the study Age between 18 and 70 years The patient should have mental health

**Exclusion criteria:**

Presence of concomitant systemic disease History of allergy to general anesthetics and epidural anesthesia Previous history of abdominal surgery Acute cholecystitis and acute pancreatitis Main bile duct stone cholangitis Having or suspecting gallbladder malignancy Having or suspecting heart failure and severe COPD Suffering or history of migraine pregnancy

**Age**From **18 years** old to **70 years** old**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients who are eligible to enter the study will be randomly assigned to two groups receiving general anesthesia and general anesthesia with epidural anesthesia.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the evaluator of pain intensity and common complications after laparoscopic cholecystectomy and the data analyzer were blinded, but the researchers were aware of the type of method used.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

One strategy that has not been studied so far in laparoscopic cholecystectomy is to combine general anesthesia with a less invasive regional analgesia method. Although this method has been previously investigated in surgeries such as abdominal aortic aneurysm, open surgery for pheochromocytoma, major abdominal surgery, open surgery for gastric cancer, etc., promising results on the effectiveness of this method in reducing postoperative complications, length It has shown the duration of hospitalization and its safety. But so far, no study has investigated this combined technique in laparoscopic cholecystectomy surgery in order to verify the feasibility of this method with the greatest effect and the least complications. Therefore, in this clinical trial research, the effectiveness of this new combined method will be investigated in patients undergoing laparoscopic cholecystectomy compared to general anesthesia

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Yasuj University of Medical Sciences

**Street address**

Shahid mottahari Blvd

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Yasuj

**Province**

Kohgiluyeh-va-Boyerahmad

**Postal code**

7591741417

**Approval date**

2023-07-19, 1402/04/28

**Ethics committee reference number**

IR.YUMS.REC.1402.077

**Health conditions studied****1****Description of health condition studied**

Pain intensity after laparoscopic cholecystectomy

**ICD-10 code**

K80.10

**ICD-10 code description**

Calculus of gallbladder with chronic cholecystitis without obstruction

## Primary outcomes

### 1

#### Description

Pain intensity :Numerical rating scale of pain intensity, which is measured by asking the patient to choose a number (between 0 and 10) and based on the McGill pain intensity scale.

#### Timepoint

Pain intensity as the main outcome in all patients in two study groups is evaluated by McGill questionnaire at the time of admission and before surgery. Then the same evaluation is done in the recovery room after the operation (zero hour) and 4, 6, 12, 24 hours after the end of the surgery.

#### Method of measurement

McGill Pain Intensity Scale Questionnaire

## Secondary outcomes

### 1

#### Description

Common complications after laparoscopic cholecystectomy :Hypotension, bradycardia, hypoxemia, headache, nausea, vomiting, right shoulder pain, abdominal discomfort related to anesthesia and pneumoperitoneum, urinary retention.

#### Timepoint

Evaluation is done in the recovery room after the operation (zero hour) and 4, 6, 12, 24 hours after the end of the surgery.

#### Method of measurement

1. Hypotension (more than 30% decrease in baseline mean arterial pressure or systolic arterial pressure less than 90 mm Hg) 2. Bradycardia (heart rate less than 50 beats per minute) 3. Hypoxemia (SpO2 less than 90) 4. Headache or not 5. Nausea and vomiting or not 6. Right shoulder pain or not 7. Abdominal discomfort or not 8. Urinary retention or not

## Intervention groups

### 1

#### Description

Intervention group: The intervention group patients will receive a single shot of epidural anesthesia with 0.06 mg/kg marcaine 0.05% and 0.14 ml/kg lidocaine 2% as an injection before receiving general anesthesia. Epidural injection in T12-L1, L1-L2 in the amount of 10-15 cc is performed with a No. 18 needle. Using 0.03 mg/kg midazolam, 14.26 mcg/kg microfentanyl, 0.11 mg/kg morphine, 2.86 mg/kg propofol and 0.71 mg/kg etracurium will be administered under general anesthesia.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: Patients in the control group will only receive general anesthesia using 0.03 mg/kg midazolam, 14.26 mcg/kg microfentanyl, 0.11 mg/kg morphine, 2.86 mg/kg propofol and 0.71 mg/kg etracurium.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Jalil Hospital

##### Full name of responsible person

Reza Hosseinpour

##### Street address

Gharani Blvd

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Yasuj

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasouj University of Medical Sciences

##### Full name of responsible person

Mohammadtaher Rezanejad

##### Street address

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##### Web page address

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor

**organization/entity?**

Yes

**Title of funding source**

Yasouj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Ali Roostapour

**Position**

Rezident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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**Full name of responsible person**

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**Position**

Associate professor

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Specialist

**Other areas of specialty/work**

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**Position**

Rezident

**Latest degree**

Medical doctor

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General Surgery

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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