

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparing postoperative pain in Laparoscopic cholecystectomy under spinal anesthesia with general anesthesia in symptomatic cholelithiasis: A randomized clinical trial

#### Protocol summary

##### Study aim

we compare postoperative pain in laparoscopic cholecystectomy under spinal anesthesia (SA) with general anesthesia in symptomatic cholelithiasis patients to show spinal anesthesia is a better technic considering pain.

##### Design

randomized clinical trial on 32 patients with a control group, parallel and non-blinded.

##### Settings and conduct

study was conducted in Aria and Farabi hospitals in Mashhad. both methods of anesthesia was done according to guidelines.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with symptomatic cholelithiasis, patients with American Society of Anesthesiologists physical status I, II, and III. Exclusion criteria: having a history of severe nausea and vomiting, using antiemetic and analgesic medication in the last 24 hours, having allergic response to anesthetics and coagulopathy disorders.

##### Intervention groups

In the intervention group, patients received spinal anesthesia, and the control group was general anesthesia.

##### Main outcome variables

Postoperative pain; mean arterial pressure; heart rate; nausea and vomiting

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200718048125N1**

Registration date: **2020-12-26, 1399/10/06**

Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**

Update count: **0**

##### Registration date

2020-12-26, 1399/10/06

##### Registrant information

###### Name

Hamed Beyzaii

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3765 5378

###### Email address

hmd\_beyzaii@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-13, 1397/03/23

##### Expected recruitment end date

2019-06-13, 1398/03/23

##### Actual recruitment start date

2018-07-14, 1397/04/23

##### Actual recruitment end date

2019-07-14, 1398/04/23

##### Trial completion date

2019-08-14, 1398/05/23

##### Scientific title

Comparing postoperative pain in Laparoscopic cholecystectomy under spinal anesthesia with general anesthesia in symptomatic cholelithiasis: A randomized clinical trial

##### Public title

Effect of spinal anesthesia on postoperative pain

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Patients diagnosed with symptomatic cholelithiasis  
Patients with body mass index of less to equal of 32 Kg/m2  
Patients with American Society of Anesthesiologists (ASA) physical status I, II, and III.

**Exclusion criteria:**  
having a history of severe nausea and vomiting in last 24 hours using antiemetics in the last 24 hours using analgesic medications in the last 48 hours having an allergic response to anesthetics having coagulopathy disorders seen deformity of vertebral bones addiction or drug abuse having skin injury in the place of injection for anesthesia

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2-3

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

**Sample size**  
Target sample size: **32**  
Actual sample size reached: **32**

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

**Randomization description**  
Simple randomization. Random numbers between 0 and 1 were generated using the calculator. Patients that received codes between 0 and 0.5 were located in general anesthesia group and patients that received codes between 0.5 and 1 were located in spinal anesthesia group.

**Blinding (investigator's opinion)**  
Not blinded

**Blinding description**

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Islamic Azad University, Mashhad branch

**Street address**

No. 8, Emam Khomeini Ave, Shahinfar Medical School

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9187147578

**Approval date**

2018-05-23, 1397/03/02

**Ethics committee reference number**

IR.IAU.MSHD.REC.1397.005

## Health conditions studied

### 1

**Description of health condition studied**

cholelithiasis

**ICD-10 code**

K80

**ICD-10 code description**

Cholelithiasis

## Primary outcomes

### 1

**Description**

Postoperative pain

**Timepoint**

during recovery and 2, 4 hours after surgery

**Method of measurement**

Visual Analogue Scale

### 2

**Description**

Heart rate

**Timepoint**

before surgery, after induction, first, second, third 15 minutes after surgery and in recovery

**Method of measurement**

Clinical examination

### 3

**Description**

Mean arterial pressure

**Timepoint**

First, second, and third 15 minutes after surgery

**Method of measurement**

Clinical examination

### 4

**Description**

Postoperative nausea and vomiting

**Timepoint**

during recovery

**Method of measurement**

Clinical examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Spinal anesthesia; 26-gauge spinal needle (Dr.J Tianjin Hanaco Medical Co. Tianjin, China) was introduced, then 0.5% Bupivacaine mixed with 0.2 µg of Sufentanil was injected at either the third or fourth lumbar epidural space with median or paramedian approach.

#### Category

Treatment - Surgery

### 2

#### Description

Control group: General anesthesia; 5 mg/kg Thiopentone Sodium, 0/5 mg/kg Atracurium Besylate, 2 mg Midazolam, 3 µg/kg Sufentanil were administered, then 100 µg/kg/min Propofol mixed with N2O were infused.

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Farabi hospital

##### Full name of responsible person

Hamed Beyzaii

##### Street address

No.1, Kowsar Blvd, Mashhad.

##### City

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##### Phone

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### 2

#### Recruitment center

##### Name of recruitment center

Aria hospital

##### Full name of responsible person

Hamed Beyzaii

##### Street address

No. 3, Pasdaran Ave, Chamran street, Mashhad.

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Islamic Azad University

##### Full name of responsible person

Saeed Abtahi

##### Street address

Shahinfar Faculty of Medicine, Imam Khomeini Ave

##### City

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+98 51 3225 6291

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IMRC@mshdiau.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Islamic Azad University

#### Proportion provided by this source

100

#### Public or private sector

Private

#### 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

Islamic Azad University

##### Full name of responsible person

Hamed Beyzaii

##### Position

Assistant professor

##### Latest degree

Specialist

##### 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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**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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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