

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

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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

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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

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No.1, Kowsar Blvd, Mashhad.

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2

Recruitment center

Name of recruitment center

Aria hospital

Full name of responsible person

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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

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Shahinfar Faculty of Medicine, Imam Khomeini Ave

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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

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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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