

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of intraoperative blood pressure and heart rate changes, postoperative nausea, vomiting and pain in two methods of epidural and general anesthesia in laparoscopic cholecystectomy

Protocol summary

Summary

Purpose: Comparison of intraoperative blood pressure and heart rate changes, postoperative nausea, vomiting and pain in two methods of epidural and general anesthesia in laparoscopic cholecystectomy. Design and criteria: This study is prospective, randomized, double-blinded and clinical trial. 66 patients candidate for laparoscopic cholecystectomy were chosen and divided randomly to same groups. For the first group, general anesthesia (GA) and for the second group, epidural anesthesia is used. Methods and interventions: After monitoring, in the first group anesthesia is induced with fentanyl 4µg/kg, 0.5mg/kg atracurium and propofol 2mg/kg and is maintained by propofol infusion, atracurium and fentanyl if needed. In the second group, patients are placed in the sitting position and using a 18-gauge tuohy needle, 15 mL of 0.5% hyperbaric bupivacaine is injected in the epidural space and the catheter inserted. Primary and secondary outcome: Blood pressure and heart rate were recorded before induction, after intubation in Group A, after catheter insertion and change the position in the second group and then every 15 minutes until the end of the surgery. After surgery, the incidence of abdominal and shoulder pain with VAS, nausea and vomiting in recovery room, 6, 12 and 24 hours later are evaluated. The onset time of pain and analgesic drug (methadone) are evaluated in the first 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305289229N3**
Registration date: **2013-06-17, 1392/03/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-17, 1392/03/27

Registrant information

Name

Mehryar Taghavi Gilani

Name of organization / entity

Medical University of Mashhad

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 5209

Email address

taghavim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Science

Expected recruitment start date

2013-05-25, 1392/03/04

Expected recruitment end date

2014-05-25, 1393/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intraoperative blood pressure and heart rate changes, postoperative nausea, vomiting and pain in two methods of epidural and general anesthesia in laparoscopic cholecystectomy

Public title

Anesthesia in laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA I, II; laparoscopic cholecystectomy

Exclusion criteria: patient's refusal; coagulopathy; ischemic heart disease; heart failure; addiction; motion sickness; previous postoperative nausea and vomiting; increasing of surgery time due to adhesion

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 66

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Mashhad University of Medical Sciences

Street address

Ghoreishi Apartment, Daneshgah street, Mashhad

City

Mashhad

Postal code**Approval date**

2013-05-25, 1392/03/04

Ethics committee reference number

910743

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

intraoperative hemodynamic changes

ICD-10 code

I97.8

ICD-10 code description

Other postprocedural disorders of circulatory system, not elsewhere classified

2**Description of health condition studied**

postoperative nausea and vomiting

ICD-10 code

K91.0

ICD-10 code description

Vomiting following gastrointestinal surgery

3**Description of health condition studied**

postoperative pain

ICD-10 code

K91.8

ICD-10 code description

Other postprocedural disorders of digestive system, not elsewhere classified

Primary outcomes**1****Description**

blood pressure

Timepoint

before of anesthesia and 15 minutes to end of surgery

Method of measurement

monitoring

2**Description**

heart rate

Timepoint

before of anesthesia and 15 minutes to end of surgery

Method of measurement

monitoring

Secondary outcomes**1****Description**

nausea

Timepoint

postoperation to 24 hours later

Method of measurement

observation and question

2**Description**

vomiting

Timepoint

postoperation to 24 hours later

Method of measurement

observation and question

3

Description

abdominal pain

Timepoint

recovery room to 24 hours later

Method of measurement

verbal analogue scale

4

Description

shoulder pain

Timepoint

recovery room to 24 hours later

Method of measurement

verbal analogue scale

Intervention groups

1

Description

control group: the patients who receive general anesthesia

Category

Treatment - Drugs

2

Description

epidural group: the patients who receive epidural anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Reza Hospital

Full name of responsible person

Mehrya Taghavi Gilani

Street address

Department of Anesthesiology, Imam Reza Hospital, Ibne Sina st, Mashhad

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Science

Full name of responsible person

Mehryar Taghavi Gilani

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mehryar Taghavi Gilani

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty