Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of general and epidural anesthesia on respiratory parameters during and after laparoscopic cholecystectomy surgery

Protocol summary

Summary

The present study aims to compare the effect of general and epidural anesthesia on respiratory parameters during and after laparoscopic cholecystectomy surgery. Samples include all patients receiving laparoscopic cholecystectomy surgery in Imam Reza University. It is a double-blind clinical trial. 58 patients are selected among all patients receiving laparoscopic cholecystectomy surgery, and are divided to two groups randomly, a group receiving general and the other receiving epidural anesthesia. After pre-medication among GA with midazolam 05.0 mg/kg, intravenous fentalyn 1 µg/kg, patients are anesthetized using propofol 2 mg/kg and atracurium 5.0 mg/kg and standard monitoring is completed. Proper indotratracheal tube is contrived and surgery starts. During the surgery, anesthetization continues through using isoflurane 1.4 1% blended with a mixture of air and 50% oxygen. Epidural set is used to inject 10 cc Lidocaine and epinephrine 1 in 200000, including 1 cc sodium bicarnonate in the space between vertebrae of the thoracic among EA group. ABG is tested during and after surgery and VC and SPO2 is measure through monitoring. Two groups are compared later. Entrance criteria includes written consent by patients; I, II ASA class; age range of 20 to 60; no history on respiratory or cardio problems; no history on diabetes or similar diseases needing treatment. Exclusion criterion is a surgery lasting more than 45 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081714333N19**
Registration date: **2014-09-07, 1393/06/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-09-07, 1393/06/16

Registrant information

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-06-15, 1393/03/25

Expected recruitment end date

2014-09-16, 1393/06/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of general and epidural anesthesia on respiratory parameters during and after laparoscopic cholecystectomy surgery

Public title

The effect of general and epidural anesthesia on respiratory parameters during and after laparoscopic cholecystectomy surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Entrance criteria includes written consent by patients; I, II ASA class; age range of 20 to 60; no history on respiratory or cardio problems; no history on diabetes or similar diseases needing treatment. Exclusion criterion is a surgery lasting more than 45 minutes.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2014-06-09, 1393/03/19

Ethics committee reference number

10218/420/7/پ

Health conditions studied

1

Description of health condition studied

Laparascopic cholecystectomy

ICD-10 code

K80.2

ICD-10 code description

Cholecystolithiasis

Primary outcomes

1

Description

FEV1

Timepoint

A day before and after surgery

Method of measurement

Using spirometry

2

Description

VC

Timepoint

During and an hour after surgery

Method of measurement

Using anesthesia machine monitor

3

Description

SPO2

Timepoint

Before, during and an hour after surgery

Method of measurement

Using pulse oxy meter monitor

4

Description

PH

Timepoint

Before, during and an hour after surgery

Method of measurement

Using blood gas analysis (ABG)

5

Description

Pao2

Timepoint

Before, during and an hour after surgery

Method of measurement

Using blood gas analysis (ABG)

6

Description

PaCo2

Timepoint

Before, during and an hour after surgery

Method of measurement

Using blood gas analysis (ABG)

7

Description

Hco3

Timepoint
Before, during and an hour after surgery
Method of measurement
Using blood gas analysis (ABG)

8

Description
FVC
Timepoint
A day before and after surgery
Method of measurement
Through spirometry

9

Description
O2SAT
Timepoint
Before, during and an hour after surgery
Method of measurement
Using blood gas analysis (ABG)

Secondary outcomes

empty

Intervention groups

1

Description
In the first group(GA), After pre-medication among GA with midazolam 05.0 mg/kg, intravenous fentalyn 1 µg/kg, patients are anesthetized using propofol 2 mg/kg and atracurium 5.0 mg/kg and standard monitoring is completed. Proper indotratracheal tube is contrived and surgery starts. During the surgery, anesthetization continues through using isoflurane 1.4 1% blended with mixture of air and 50% oxygen. During the surgery ABG is tested and SPO2 is measured accordingly. An hour later, during recovery period, ABG is retested and VC and SPO2 are measured through monitoring.
Category
Treatment - Surgery

2

Description
In the second group (EA), 10 cc Lidocaine and epinephrine 1 in 200000, including 1 cc sodium bicarnonate for each 10 cc of Lidocaine, would be injected in the space between vertebrae of the thoracic using epidural set. ABG and SPO2 would be measured during surgery. ABG would be measured again, and VC and SPO2 would be checked using monitor an hour after surgery during recovery period.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Dr.iraj Peiman
Street address
Emam Reza Hospital,Razi Boulvard,Sorkhleje
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
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 Affairs, Kermanshah University of Medical Sciences
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Ali karbasforushan
Position
Anesthesiologist

Other areas of specialty/work
Street address
Emam Reza Hospital,Razi Boulvard,Sorkhleje
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Fax
Email
ali_karbasfrushan@yahoo.com
Web page address

Person responsible for updating data

Contact

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