Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of different levels of positive end-expiratory pressure on the respiratory function in laparoscopic cholecystectomy candidates

Protocol summary

Study aim
Comparison of 0, 5 and 7 cm H2O positive end-respiratory pressure on the respiratory function of laparoscopic cholecystectomy candidates

Design
Phase III single-blind (assessor-blind) randomized controlled trial with parallel groups on 75 patients, randomization will be performed using a randomization table generated by the Random Allocation software.

Settings and conduct
This study will be performed on 75 laparoscopic cholecystectomy candidates in Shahid Mohammadi Hospital, Bandar Abbas. Patients will be randomized into three groups based on a randomization table. Patients in intervention groups 1 and 2 and the control group will receive positive end-expiratory pressure of 5, 7, and 0 cm H2O, respectively. The respiratory and cardiac parameters will be assessed by an individual blinded to patient grouping (assessor-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 18-70 years, ASA class I and II Exclusion criteria: hemodynamic instability, severe heart failure, renal failure, respiratory failure, pulmonary embolism, air embolism during the operation, complications of laparoscopy leading to laparotomy, history of chronic respiratory diseases, asthma, and chronic obstructive pulmonary disease

Intervention groups
Intervention group 1: positive end-expiratory volume (PEEP) of 5 cm H2O Intervention group 2: PEEP of 7 cm H2O Control group: PEEP of 0 cm H2O

Main outcome variables
Partial pressure of oxygen in arterial blood (PaO2)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058854N1**
Registration date: **2023-07-24, 1402/05/02**
Registration timing: **prospective**

Last update: **2023-07-24, 1402/05/02**
Update count: **0**

Registration date
2023-07-24, 1402/05/02

Registrant information

Name
Zohre Nikeghbali

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3371 0393

Email address
zohrenikeghbal77@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-08-06, 1402/05/15

Expected recruitment end date
2024-02-04, 1402/11/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of different levels of positive end-expiratory pressure on the respiratory function in laparoscopic cholecystectomy candidates

Public title

The effect of different levels of positive end-expiratory pressure on respiratory function in laparoscopic cholecystectomy candidates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-70 years ASA class I and II

Exclusion criteria:

Hemodynamic instability Severe heart failure Renal failure Respiratory failure Pulmonary embolism Air embolism during the operation Complications of laparoscopy leading to laparotomy History of chronic respiratory diseases, asthma, and chronic obstructive pulmonary disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized into two groups using simple randomization with individuals as the unit of randomization and a randomization table produced by the Random Allocation software. An individual uninvolved in the study will write A or B or C on a card and put it in an opaque envelope. Then the associated number in the randomization table will be written on the back of the envelope. One envelope will be allocated to each patient in order of entrance to the study. Allocation concealment will be done using opaque envelopes.

Blinding (investigator's opinion)

Single blinded

Blinding description

The individual responsible for the assessment of hemodynamic and respiratory parameters will be unaware of patient grouping, while given the nature of the intervention and that there is no placebo, the patient and those related to the patient will not be blinded. Therefore, the study will be single-blind with blinding the assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Faculty of Medicine, Across from Kargaran Sports Complex, Imam Hossein Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2023-04-08, 1402/01/19

Ethics committee reference number

IR.HUMS.REC.1402.094

Health conditions studied

1

Description of health condition studied

Respiratory support during elective laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Partial pressure of arterial oxygen

Timepoint

30 min after intubation

Method of measurement

Arterial blood gas (ABG)

Secondary outcomes

1

Description

Partial pressure of carbon dioxide in arterial blood

Timepoint

30 min after intubation

Method of measurement

Arterial blood gas (ABG)

2

Description

pH

Timepoint

30 min after intubation

Method of measurement

Arterial blood gas (ABG)

3

Description
End-tidal carbon dioxide (EtCO2)
Timepoint
Some minutes before laryngoscopy, during laryngoscopy, and then 15, 30, and 60 min after intubation
Method of measurement
Capnography

4

Description
Blood pressure
Timepoint
Some minutes before laryngoscopy, during laryngoscopy, and then 15, 30, and 60 min after intubation, and after extubation in the recovery unit
Method of measurement
The monitoring device

5

Description
Heart rate
Timepoint
Some minutes before laryngoscopy, during laryngoscopy, and then 15, 30, and 60 min after intubation, and after extubation in the recovery unit
Method of measurement
The monitoring device

6

Description
Oxygen saturation (SpO2)
Timepoint
Some minutes before laryngoscopy, during laryngoscopy, and then 15, 30, and 60 min after intubation, and after extubation in the recovery unit
Method of measurement
Pulse oximeter

Intervention groups

1

Description
Intervention group: Positive end-expiratory pressure of 5 cm H2O
Category
Other

2

Description
Intervention group: Positive end-expiratory pressure of 7 cm H2O
Category
Other

3

Description
Control group: Positive end-expiratory pressure of 0 cm H2O
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Mohammadi Hospital
Full name of responsible person
Zohre Nikeghbali
Street address
Shahid Mohammadi Hospital, Jomhouri Eslami Blvd., Hormozgan, Iran
City
Bandar Abbas
Province
Hormozgan
Postal code
9791991551
Phone
+98 76 3334 7000
Email
shmh@hums.ac.ir
Web page address
https://shmh.hums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery for Research Hormozgan University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Faculty of Medicine, Across from Kargaran Sports Complex, Imam Hossein Blvd.
City
Bandar Abbas
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Postal code
7919693116
Phone
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Email
teaghamolaei@gmail.com
Web page address
https://resv.hums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellery for Research Hormozgan 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Zohre Nikeghbali

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available