

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-expiratory 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, Jomhuri Eslami Blvd., Hormozgan, Iran

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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.

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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

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

Across from Kargaran Sports Complex, Imam Hossein Blvd., Bandar Abbas, Hormozgan, Iran

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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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Latest degree

Medical doctor

Other areas of specialty/work

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Street address**Person responsible for updating data****Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

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Position

Intern

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Fax**Email**

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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