Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of different levels of positive end-expiratory pressure (PEEP) on respiratory status during gynecologic laparoscopy

Protocol summary

Study aim

1. Comparison of pH alteration during gynecologic laparoscopy between study groups. 2. Comparison of HCO3 alteration during gynecologic laparoscopy between study groups. 3. Comparison of PCO2 alteration during gynecologic laparoscopy between study groups. 4. Comparison of Base excess (BE) alteration during gynecologic laparoscopy between study groups. 5. Comparison of PO2 alteration during gynecologic laparoscopy between study groups. 6. Comparison of O2 saturation (Sat PO2) alteration during gynecologic laparoscopy between study groups. 7. Comparison of ET CO2 alteration during gynecologic laparoscopy between study groups.

Design

In current double-blinded randomized clinical trial, 36 women candidate to undergo laparoscopic gynecological surgery, aged between 18 and 60 years old with ASA class I physical status will be enrolled. Patients will be randomly assigned to study groups, considering positive end-expiratory pressure (PEEP) rate: ZEEP group will undergo routine PPV without PEEP administration, PEEP5 group will receive PEEP: 5cm H2O in addition to routine PPV and PEEP10 group will receive PEEP: 10cm H2O in addition to routine PPV and a code will be allocated to each of participants.

Settings and conduct

Current investigation will be performed in Obstetrics and Gynecology center in Tabriz. In present study, patients, investigator, care provider, outcome assessor and data analyzer are blinded to participants study groups. The anesthesiologist will be responsible for data collection and outcome assessing, will not be aware of interventions and study group.

Participants/Inclusion and exclusion criteria

In current double-blinded randomized clinical trial, 36 women candidate to undergo laparoscopic gynecological surgery, aged between 18 and 60 years old with ASA class I physical status will be enrolled and patient with systemic and psychotic disorders will be excluded.

Intervention groups

Maintenance of general anesthesia will be done via midazolam, remifentanil, propofol and atracurium. Positive pressure ventilation (PPV) with volume controlled ventilation (VCV) will be applied as follows, tidal volume of 8-10 ml per minute, respiratory rate of 12 per minute and 1 to 2 rate of inhalation and exhalation. Patients will be randomly assigned to study groups, considering positive end-expiratory pressure (PEEP) rate: ZEEP group will undergo routine PPV without PEEP administration, PEEP5 group will receive PEEP: 5cm H2O in addition to routine PPV and PEEP10 group will receive PEEP: 10cm H2O in addition to routine PPV and a code will be allocated to each of participants.

Main outcome variables

Hemodynamic variables including heart rate, systolic and diastolic blood pressure, mean arterial pressure and arterial oxygen saturation will be measured before induction of anesthesia, immediately after induction, at 5th,10th, 20th, 30th, 60th minutes and at the end of operation. In addition, surgery duration, anesthesia duration, duration of pneumoperitoneum, administered intravenous fluid volume, volume of blood loss, urine output and dysrhythmia incidence with regard to its type, will be recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110712007013N19**
Registration date: **2017-12-17, 1396/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-17, 1396/09/26**
Update count: **0**

Registration date

2017-12-17, 1396/09/26

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Siences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of different levels of positive end-expiratory pressure (PEEP) on respiratory status during gynecologic laparoscopy

Public title

Effect of positive end-expiratory pressure (PEEP) on patients intraoperative respiratory status

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

American society of Anesthesiology (ASA) class I aged between 18-60 years old candidate for laparoscopic gynecological surgery interest to participate in study

Exclusion criteria:

patients with ASA class II or higher not inclined to take part in study body mass index greater than 30 kg/m2 systemic disorders psychotic disorders emergent surgery smokers history of atopic disorders

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified block randomization method used to randomly allocation of patients to study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In present study, patients, investigator, care provider, outcome assessor and data analyzer are blinded to participants study groups. The study team includes an anesthesiologists, who is responsible for data collection and outcome assessing, who is not in charge of anesthesia management, thus is not aware of interventions and study group. In addition, all study groups and subsequent interventions will be introduced to the patients and it will been mentioned in the written consent that patients will be blinded to the study groups and interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2017-01-15, 1395/10/26

Ethics committee reference number

IR.TBZMED.REC.1395.1277

Health conditions studied

1

Description of health condition studied

Hemodynamic changes during gynecological surgery

ICD-10 code

I97

ICD-10 code description

Postprocedural disorders of circulatory system, not elsewhere classified

Primary outcomes

1

Description
Heart Rate
Timepoint
before induction of anesthesia, immediately after induction, at 5th,10th, 20th, 30th, 60th minutes and at the end of operation
Method of measurement
Questionnaire

2

Description
Systolic blood pressure
Timepoint
before induction of anesthesia, immediately after induction, at 5th,10th, 20th, 30th, 60th minutes and at the end of operation
Method of measurement
Monitor sphygmomonometer

3

Description
Dyastolic blood pressure
Timepoint
before induction of anesthesia, immediately after induction, at 5th,10th, 20th, 30th, 60th minutes and at the end of operation
Method of measurement
Monitor sphygmomonometer

4

Description
Arterial blood oxygen saturation
Timepoint
before induction of anesthesia, immediately after induction, at 5th,10th, 20th, 30th, 60th minutes and at the end of operation
Method of measurement
Monitor pulseoximeter

Secondary outcomes

1

Description
Urinary output volume
Timepoint
At the end of operation
Method of measurement
Urine bag

2

Description
Blood loss volume
Timepoint
At the end of operation
Method of measurement
Suction device tank

Intervention groups

1

Description
Control group: 12 patients will recieve zero end-expiratory pressure, in addition to PPV.
Category
Other

2

Description
Intervention group: Intervention group: 12 patients will receive PEEP with pressure of 5 cmH2O, in addition to PPV.
Category
Treatment - Other

3

Description
Intervention group: 12 patients will receive PEEP with pressure of 10 cmH2O, in addition to PPV.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra Women's Hospital
Full name of responsible person
Dr. Simin Atashkhoyi
Street address
Baghshomal crossroad
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Tabriz
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5183915881
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Alireza Ostadrahimi
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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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Simin Atashkhoyi
Position
Professor, Specialist in Anesthesiology
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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

Title and more details about the data/document

All collected deidentified IPD will be shared.

When the data will become available and for how long

Th data will be available for 1 year, starting 3 months after publication.

To whom data/document is available

The data will be available only for academic institutions.

Under which criteria data/document could be used

Not decided.

From where data/document is obtainable

atashkhoii@tbzmed.ac.ir

What processes are involved for a request to access data/document

In order to acquire study data, the applicants should send an email containing their purpose and sufficient information about their work.

Comments