

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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, remifentanyl, 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 Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 3806

Email address

atashkhoei@tbzmed.ac.ir

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 be 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 sphygmomanometer

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 sphygmomanometer

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 receive 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

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Phone

+98 41 3553 9161

Email

atashkhoyi@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Phone

+98 41 3553 9161

Email

ostadrahimia@tbzmed.ac.ir

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

Anesthesiology

Street address

Basghshomal coss road

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Phone

+98 41 3553 9161

Email

atashkhoyi@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Baghshomal crossroad

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Phone

+98 41 3553 9161

Email

atashkhoyi@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Baghshomal Crossroad

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Phone

+98 41 3553 9161

Email

atashkhoyi@tbzmed.ac.ir

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

The 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

atashkhooii@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