

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Determining the effect of low positive end-expiratory pressure (PEEP) on hemodynamic status in patients undergoing gynecologic laparoscopy: A double-blinded clinical trial

Protocol summary

Summary

In current double-blinded randomized clinical trial, 80 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. 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: case group (PEEP, n=40) in association with PPV will receive low PEEP with pressure of 5 cmHg and control group (zero end-expiratory pressure (ZEEP) ,n=40) will receive PPV without PEEP. 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. An anesthesiologist will manage the anesthesia and monitor the patients, however second anesthesiologist who will be blinded to patients study group, will record the study variables.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706057013N18**

Registration date: **2017-06-28, 1396/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-28, 1396/04/07

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

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of low positive end-expiratory

pressure (PEEP) on hemodynamic status in patients undergoing gynecologic laparoscopy: A double-blinded clinical trial

Public title

Effects of positive end-expiratory pressure on hemodynamic 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

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

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

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, Tabriz university of medical sciences, Daneshgah square

City

Tabriz

Postal code

Approval date

2016-04-25, 1395/02/06

Ethics committee reference number

IR.TBZMED.REC.1395.937

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

Questionnaire

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

Questionnaire

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

Questionnaire

Secondary outcomes

1

Description

Urinary output volume

Timepoint

At the end of operation

Method of measurement

Questionnaire

2

Description

Blood loss volume

Timepoint

At the end of operation

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention group: 40 patients will receive low PEEP with pressure of 5 cmHg, in addition to PPV.

Category

Treatment - Other

2

Description

Intervention group: 40 patients zero end-expiratory pressure, in addition to PPV.

Category

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, North artesh street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of Medical Sciences

Full name of responsible person

Alireza Ostadrahimi

Street address

Vice chancellor for research, Tabriz University of medical sciences, Daneshgah square

City

Tabriz

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 of Tabriz 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

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Simin Atashkhoyi

Position

Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Postal code

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