Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, 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: 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 Siences

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 3806

Email address

atashkhoii@tbzmed.ac.ir

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 disoders.
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 sceinces, 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 sceinces, 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
Street address
Al Zahra hospital, Baghshomal square
City
Tabriz
Postal code
Phone
+98 41 3553 9161
Fax
Email
atashkhoii@tbzmed.ac.ir
Web page address

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, Specialist in anesthesiology
Other areas of specialty/work
Street address
Al Zahra hospital, Baghshomal square
City
Tabriz

Postal code
Phone
+98 41 3553 9161
Fax
Email
atashkhoii@tbzmed.ac.ir
Web page address

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, Specialist in Anesthesiology
Other areas of specialty/work
Street address
Al Zahra hospital, Baghshomal square
City
Tabriz
Postal code
Phone
+98 41 3553 9161
Fax
Email
atashkhoii@tbzmed.ac.ir
Web page address

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