Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Different Levels of Positive End-expiratory Pressure (PEEP) on Respiratory Status during Gynecologic Laparoscopy

Protocol summary

Study aim

Evaluating the Effect of Different Levels of Positive End-expiratory Pressure (PEEP) on Respiratory Status during Gynecologic Laparoscopy

Design

The study protocol was approved by ethics committee of Tabriz University of Medical Sciences. After obtaining informed consent from 60 consecutive women the randomization was done. Anesthesiologist designed the groups stratification via sealed and coded envelope.

Settings and conduct

The double-blind technique was used to blind both the participants and members of the research teams including principal investigators, surgeons, anesthesiologists, nurses, data collectors, outcome assessors, and manuscript writes.

Participants/Inclusion and exclusion criteria

Inclusion criteria: American Society of Anesthesiologists [ASA] physical status I, aged 18-60 years gynecologic laparoscopy Exclusion criteri: ASA physical status II or more, BMI > 30, systemic diseases including cardio-cerebrovascular, hepato-renal and respiratory disease, psychological disorders, emergency surgery, cigarette smoker, having the history of atopy, refuse to participate.

Intervention groups

Consecutive patients were selected based on their entrance. Technique of randomization was performed via randomly permuted blocks using online software (www.randomizer.org). After that, patients were randomized to treatment by 1:1:1 ratio. randomization stratified by online rand list software to three groups: PEEP 0 (ZEEP which receive zero level of PEEP), PEEP 5 (receive PEEP of 5 cmH2O) and PEEP 10 (receive PEEP of 10 cmH2O).

Main outcome variables

Base excess; End-tidal carbon dioxide; Bicarbonate; Partial pressure of oxygen; Partial arterial pressure of carbon dioxide; Peripheral capillary oxygen saturation; Potential of hydrogen

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191019045155N1**
Registration date: **2019-12-08, 1398/09/17**
Registration timing: **retrospective**

Last update: **2019-12-08, 1398/09/17**
Update count: **0**

Registration date

2019-12-08, 1398/09/17

Registrant information

Name

Negin Yavari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 9600

Email address

negin.yavarii@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

2017-12-03, 1396/09/12

Actual recruitment end date

2018-12-04, 1397/09/13

Trial completion date

2018-12-04, 1397/09/13

Scientific title
Effect of Different Levels of Positive End-expiratory Pressure (PEEP) on Respiratory Status during Gynecologic Laparoscopy

Public title
PEEP and respiratory status
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria:
American Society of Anesthesiologists physical status I Age between 18-60 gynecologic laparoscopy
Exclusion criteria:
American Society of Anesthesiologists physical status II or more Body mass index > 30 kg/m2 Cardio-cerebrovascular disease Hepatic disease Renal disease Psychological disorders Respiratory disease Cigarette smoker Emergency surgery History of atopy Refuse to participate
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Actual sample size reached: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Consecutive patients were selected based on their entrance. Technique of randomization was performed via randomly permuted blocks using online software (www.randomizer.org). After that, patients were randomized to treatment by 1:1:1 ratio. randomization stratified by online rand list software to three groups: PEEP 0 (ZEEP), PEEP 5 and PEEP 10.
Blinding (investigator's opinion)
Double blinded
Blinding description
Double blind technique was used to blind both the participants and members of the research teams including principle investigator, surgeons, anesthesiologist, nurses, data collectors, outcome assessors and manuscript writes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences St.
City
Tabriz
Province
East Azarbaijan
Postal code
51664
Approval date
2016-11-21, 1395/09/01
Ethics committee reference number
1395.1277.IR.TBZMED.REC

Health conditions studied

1

Description of health condition studied
respiratory statues
ICD-10 code
J98.6
ICD-10 code description
Disorders of diaphragm

2

Description of health condition studied
respiratory statues
ICD-10 code
J98.11
ICD-10 code description
Atelectasis

3

Description of health condition studied
Respiratory status
ICD-10 code
Y76.1
ICD-10 code description
Therapeutic (nonsurgical) and rehabilitative obstetric and gynecological devices associated with adverse incidents

Primary outcomes

1

Description
Respiratory Status
Timepoint
During gynecologic laparoscopy

Method of measurement
Laboratory data

Secondary outcomes

1

Description
PH
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

2

Description
HCO3
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

3

Description
PaCO2
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

4

Description
PaO2
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

5

Description
Base excess
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

6

Description
SPO2
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

7

Description
ETCO2
Timepoint
During gynecologic laparoscopy
Method of measurement
Laboratory data

Intervention groups

1

Description
Intervention group: Positive End-expiratory Pressure 5 cmH2O
Category
Prevention

2

Description
Intervention group: Positive End-expiratory Pressure 10 cmH2O
Category
Prevention

3

Description
Control group: Positive End-expiratory Pressure 0 cmH2O
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Mahsa Zarrintan
Street address
Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
51664
Phone
+98 41 3334 1994
Email
mahsa_zarrintan@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy, Faculty of Medicine, Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Samiei

Street address
Tabriz University of Medical Sciencse St.
City
Tabriz
Province
East Azarbaijan
Postal code
51644
Phone
+98 41 3334 1994
Email
mahsa_zarrintan@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Deputy, Faculty of Medicine, 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
Mahsa Zarrintan
Position
Specialist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Tabriz Univerisity of Medical Sciences St.
City
Tabriz
Province
East Azarbaijan
Postal code
51664
Phone
+98 41 3334 1994
Email
mahsa_zarrintan@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahsa Zarrintan
Position
Specialist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Tabriz University of Medical Sciences St.
City
Tabriz
Province
East Azarbaijan
Postal code
51664
Phone
+98 41 3334 1994
Email
mahsa_zarrintan@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mahsa Zarrintan
Position
Specialist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Tabriz Univeristy of Medical Sciences St.
City
Tabriz
Province
East Azarbaijan
Postal code
51664
Phone
+98 41 3334 1994
Email
mahsa_zarrintan@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the data will be available under the name of supplementary.

When the data will become available and for how long

All the data will be available after the publication of the article forever

To whom data/document is available

Data will be available to everybody upon request

Under which criteria data/document could be used

Data could be used by other researchers for meta-analysis and systematic review

From where data/document is obtainable

Data will be available as a supplementary file to the published article

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

The data will be available upon request, forever.

Comments