# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jul 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
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**Province**
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**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**
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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**
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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**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**