

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 2026

### Comparing the changes in hemodynamic and respiratory parameters in two methods of spinal anesthesia versus general anesthesia in diagnostic gynecologic laparoscopy

#### Protocol summary

##### Study aim

Reduction of hemodynamic and respiratory complications in diagnostic laparoscopic gynecological surgeries of woman by choosing the type of anesthesia (general anesthesia or spinal anesthesia)

##### Design

Clinical trial with intervention and control groups, with parallel groups, unidirectional blinded, randomized, sample of 74 patients. Rand list software was used for randomization.

##### Settings and conduct

All patients who are candidates for diagnostic laparoscopic gynecology at Al-Zahra Hospital in Tabriz will be included in this study. Patients are randomly assigned to intervention and control groups, in which, the intervention group spinal anesthesia and in the control group, general anesthesia will be applied. To compare the hemodynamic and respiratory consequences in these patients. In this study, only the data analyzer are blinded to the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Female with physical condition ASA (American Society of Anesthesiologists) class I or II, In the age range of 60-18 years, candidate for laparoscopic gynecological surgery, Patient consent to study. Exclusion criteria: Existence of any contraindications to regional anesthesia, Sensitivity to local anesthetics, Excessive obesity, Accompanying systemic diseases such as any history of cardiovascular, pulmonary, hepatic, renal, etc.

##### Intervention groups

Control group: 34 patients will undergo general anesthesia and the hemodynamic and respiratory consequences will be evaluated. Intervention group: 34 patients will undergo spinal anesthesia and the hemodynamic and respiratory consequences will be evaluated.

#### Main outcome variables

Systolic and diastolic blood pressure, Mean arterial pressure, Heart rate, Saturation of peripheral oxygen, Severity of postoperative nausea and vomiting, Severity of postoperative pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180411039267N4**  
Registration date: **2021-02-15, 1399/11/27**  
Registration timing: **registered\_while\_recruiting**

Last update: **2021-02-15, 1399/11/27**

Update count: **0**

##### Registration date

2021-02-15, 1399/11/27

##### Registrant information

##### Name

Reyhaneh Abri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3476 7121

##### Email address

re.abri@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-29, 1399/11/10

##### Expected recruitment end date

2021-07-01, 1400/04/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the changes in hemodynamic and respiratory parameters in two methods of spinal anesthesia versus general anesthesia in diagnostic gynecologic laparoscopy

**Public title**

Comparison of hemodynamic and respiratory changes in anesthesia and laparoscopic gynecological surgeries

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Female with physical condition ASA(American Society of Anesthesiologists) class I or II In the age range of 60-18 years candidate for laparoscopic gynecological surgery Patient consent to study

**Exclusion criteria:**

Existence of any contraindications to regional anesthesia Sensitivity to local anesthetics Excessive obesity Accompanying systemic diseases such as any history of cardiovascular, pulmonary, hepatic, renal, etc.

**Age**

From **18 years** old to **60 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Data analyser

**Sample size**

Target sample size: **74**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using a table of random numbers that includes numbers from 1 to 74 and with each referral up to 74th patient,each time we randomly select a number from the number table(by calculators random numbers system and each number will have a chance to happen only once) and depending on what number comes up,each patient is placed in one of the two intervention groups (37 people) and the control group (37 people).Thus,if our random number was odd, the patient will be in the intervention group and will undergo spinal anesthesia and if our random number was even,the patient will undergo general anesthesia in the control group.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

In this study, the anesthesiologist is fully aware of the groupings because he has to induce general anesthesia and anesthesia on patients. The same anesthesiologist and nurse collected the data during the operation and recovery, and the patient are Conscious of anesthesia or

numbness, and only the data analyzer is blind to the study.

**Placebo**

Not used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethic 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**

2021-01-25, 1399/11/06

**Ethics committee reference number**

IR.TBZMED.REC.1399.973

**Health conditions studied****1****Description of health condition studied**

Comparison of hemodynamic and respiratory changes in spinal anesthesia and general anesthesia in diagnostic laparoscopy in women

**ICD-10 code**

T88.59

**ICD-10 code description**

Other complications of anesthesia

**Primary outcomes****1****Description**

Systolic and diastolic blood pressure

**Timepoint**

From the beginning of anesthesia to 30th minute,every 5 minutes and after that every 15minutes and in recovery section until discharging,every 10 minutes.

**Method of measurement**

Mercury barometer

**2****Description**

Mean arterial pressure(MAP)

#### **Timepoint**

From the beginning of anesthesia to 30th minute, every 5 minutes and after that every 15 minutes and in recovery section until discharging, every 10 minutes.

#### **Method of measurement**

Mercury barometer

### **3**

#### **Description**

Heart rate

#### **Timepoint**

From the beginning of anesthesia to 30th minute, every 5 minutes and after that every 15 minutes and in recovery section until discharging, every 10 minutes.

#### **Method of measurement**

Counting in each minutes

### **4**

#### **Description**

Saturation of peripheral oxygen

#### **Timepoint**

From the beginning of anesthesia to 30th minute, every 5 minutes and after that every 15 minutes and in recovery section until discharging, every 10 minutes.

#### **Method of measurement**

Via the Pulse Oximeter

## **Secondary outcomes**

### **1**

#### **Description**

Severity of postoperative nausea and vomiting

#### **Timepoint**

Every 5 minutes in recovery until discharge from recovery and transfer to ward

#### **Method of measurement**

scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

### **2**

#### **Description**

Severity of postoperative pain

#### **Timepoint**

Recovery and at 3, 6, 12, 18 and 24 hours postoperatively

#### **Method of measurement**

Four Numerical Verbal Rating Scale

## **Intervention groups**

### **1**

#### **Description**

Control group: 37 patients will be placed under general anesthesia with induction and maintenance of anesthesia with 1% intravenous propofol drug of Dongkook pharmaco company made in Korea and endotracheal intubation will be performed for controlled breathing

during surgery and hemodynamic and respiratory consequences (such as Systolic and diastolic blood pressure, mean arterial pressure, heart rate, saturation of peripheral oxygen, severity of nausea and vomiting, severity of pain )during and after surgery will be assessed.

#### **Category**

Prevention

### **2**

#### **Description**

Intervention group: 37 patients undergoing spinal anesthesia with spinal injection of topical anesthetic bupivacaine 5% hyperbaric manufactured by aspen company and spontaneous respiration will be maintained and hemodynamic and respiratory consequences (such as systolic and diastolic blood pressure, mean arterial pressure, heart rate, saturation of peripheral oxygen, severity of nausea and vomiting, severity of pain) during and after surgery will be assessed.

#### **Category**

Prevention

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra hospital

##### **Full name of responsible person**

Reyhaneh Abri

##### **Street address**

Alzahra hospital, South artesh street

##### **City**

Tabriz

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alzahrahosp@tbzmed.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr Abolghasem Joyban

##### **Street address**

Vice chancellor for research, Daneshgah street, Tabriz

##### **City**

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##### **Province**

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research-vice@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**

Reyhaneh Abri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

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**Full name of responsible person**

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## Person responsible for updating data

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**Name of organization / entity**

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**Position**

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**Latest degree**

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## 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 potential data can be shared after making peoples unrecognizable.

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

Documents will be available for people working in academic institutions and also people working in

businesses

**Under which criteria data/document could be used**

There will be no specific limitations to the utilization of the data

**From where data/document is obtainable**

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

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

**Comments**