Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

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+98 41 3476 7121

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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 15minutes 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 15minutes 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 15minutes 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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
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Anesthesiology
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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