Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Comparison of Gynecologic Laparoscopic Surgeries under Spinal Anesthesia with General Anesthesia.

Protocol summary

Study aim
Performing the gynecologic laparoscopic surgeries under spinal anesthesia considering intraoperative pain.

Design
(General anesthesia or spinal anesthesia) Designing Clinical trial with intervention and control groups, with parallel groups, single blind, randomized, sample of 80 patients for research. Rand list software was used for randomization.

Settings and conduct
All patients who are candidates for diagnostic laparoscopy in Alzahra Hospital in Tabriz will be included in this study. Patients are randomly assigned to intervention and control groups. In 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 is blinded to the study.

Participants/Inclusion and exclusion criteria
inclusion criteria: 60-18-years-old women in need of laparoscopic surgery exclusion criteria: Contraindications to laparoscopic surgery

Intervention groups
Control group: 40 patients underwent general anesthesia and the possibility of surgery due to pain and hemodynamic and respiratory consequences will be evaluated. Intervention group: 40 patients underwent spinal anesthesia the possibility of surgery due to pain and hemodynamic and respiratory consequences will be evaluated.

Main outcome variables
Systolic and diastolic blood pressure, mean arterial pressure, heart rate, peripheral oxygen saturation, severity of postoperative nausea and vomiting, severity of postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211103052950N1**
Registration date: **2022-01-27, 1400/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-27, 1400/11/07**
Update count: **0**

Registration date
2022-01-27, 1400/11/07

Registrant information

Name
Fatemeh Tabatabaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3326 2754

Email address
drtabatabaeigyn@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-22, 1400/09/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of Gynecologic Laparoscopic Surgeries under Spinal Anesthesia with General Anesthesia.

Public title

Comparison of Gynecologic Laparoscopic Surgeries under Spinal Anesthesia with General Anesthesia.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female with ASA class I _ II physical condition Candidate for gynecological laparoscopic surgery in the age range of 18-60 years in Alzahra Hospital, Tabriz Laparoscopic uterine adnexal surgeries include cystectomy, salpingectomy, oophorectomy, and ectopic pregnancy, all of which are almost identical in terms of surgery time and difficulty. Patient consent to study

Exclusion criteria:

Hemoglobin less than 10 Unusual bleeding during surgery and the need for transfusions of blood and blood products Need to convert surgery to laparotomy Existence of any contraindications to spinal anesthesia Sensitivity to local spinal anesthetics Obesity history of multiple surgeries more than twice, history of previous myomectomy,History of previous intra-abdominal adhesions Accompanying systemic diseases such as any history of cardiovascular, pulmonary, hepatic, renal, etc. Grade three and four gynecological surgeries include hysterectomy, resection of tubo-ovarian abscesses, advanced endometriosis, myomectomy, abdominal cerclage, resection of the lateral horn of the uterus, and any disease with intra-abdominal adhesions.

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: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a table of random numbers that includes numbers from 1 to 80 with each patient up to the 80th , we randomly select a number from the number table each time (by the random selection system of the calculator and each number will have a chance to happen only once) and according to the number displayed each patient in one of the two intervention groups (40 people And the control group (40 people) are placed in such a way that if our random number is an odd number, the patient will be in the intervention group and under spinal anesthesia, and if the random number is even, the patient in the control group will undergo general anesthesia. Sample size: 80 Randomization from the researcher's point of view: random assignment to intervention and control groups Description of randomization: Randomization will be done by random blocks. In this study, in order to create a balance in the number of samples assigned to each of the study groups, the block randomization method will be used. Random allocation soft ware software will be used as a randomization tool that this software In addition to randomization, it is able to generate random sequences by blocking method. For concealment, allocation concealment will be used, which is the method used to execute random sequences on study participants so that the assigned group is not known before the individual is assigned. Assigned to study groups: Parallel

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the anesthesiologist is completely aware of the groupings because he has to induce general anesthesia and spinal anesthesia on the patients. The same anesthesiologist and nurse collected the data during the operation and recovery, and the patient Is aware of anesthesia and only data analyzer blind to the study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Golgasht St., Deputy of Research and Technology City

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2021-10-25, 1400/08/03

Ethics committee reference number

IR.TBZMED.REC.1400.690

Health conditions studied

1

Description of health condition studied

Comparison of laparoscopic gynecological surgeries with spinal anesthesia and general anesthesia

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description
Ability to perform surgery according to the severity of pain during surgery
Timepoint
Operation time
Method of measurement
Visual analog scoring (all the time during operation, whenever the pain is more than 4 based on the analog visual score, a sedative and analgesic drug is prescribed and general anesthesia is induced if the surgery is not tolerated.)

Secondary outcomes

1

Description
Severe postoperative nausea and vomiting
Timepoint
Every 5 minutes in recovery until discharge from recovery and transfer to ward)
Method of measurement
How to measure the variable based on scoring (0 = no nausea and vomiting, 1 = nausea, 2 = vomiting and 3 = vomiting more than 2 times

2

Description
Severe postoperative pain
Timepoint
Recovery at 3, 6, 12, 18 and 24 hours after surgery
Method of measurement
verbal rating scale four numbers

3

Description
peripheral O2 saturation
Timepoint
Measurement intervals from the beginning of anesthesia every 5 minutes and in recovery until discharge every 10 minutes.
Method of measurement
Pulse oximeter device

4

Description
heart beat
Timepoint
Measurement intervals from the beginning of anesthesia every 5 minutes and in recovery until discharge every 10 minutes.
Method of measurement
Counting the heart beats per minutes

5

Description
Mean arterial pressure
Timepoint
Measurement intervals from the beginning of anesthesia every 5 minutes and in recovery until discharge every 10 minutes
Method of measurement
Mercury barometer

Intervention groups

1

Description
Control group: 40 patients will be placed under general anesthesia with induction and maintenance of anesthesia with intravenous drug propofol 1% Dongkook pharmaco made in Korea and endotracheal intubation will be performed for controlled breathing during surgery and possibility of surgery according to the pain severity, hemodynamic and respiratory consequences (such as systolic blood pressure and Diastolic, mean arterial pressure, heart rate, peripheral oxygen saturation, severity of nausea and vomiting, pain intensity) will be monitored during and after surgery.
Category
Prevention

2

Description
Intervention group: 40 patients undergoing spinal anesthesia with spinal injection of topical anesthetic bupivacaine 5% hyperbaric aspen and the patient's spontaneous respiration will be maintained and possibility of surgery according to the pain severity, hemodynamic and respiratory consequences (such as systolic and diastolic blood pressure, moderate pressure Arterial, heart rate, peripheral oxygen saturation, severity of nausea and vomiting, pain intensity) will be monitored during and after surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Doctor فاطمه tabatabaei
Street address
South Army Street, Al-Zahra Hospital, Tabriz, East Azerbaijan Province
City
Tabriz
Province
East Azarbaijan

Postal code
5138663134
Phone
+98 41 3553 9163
Email
alzahrahosp@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Doctor abolghasem joyban
Street address
Tabriz St., Daneshgah St., Vice Chancellor for Research, Tabriz University of Medical Sciences
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 7310
Fax
+98 41 3335 7310
Email
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
Doctor fateme tabatabaei
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
South Army Street - Al-Zahra Hospital - Operating Room of Tabriz, East Azerbaijan Province
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3476 7121
Fax
+98 41 3334 1994
Email
Drtabatabaeigyn@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Doctor fateme tabatabaei
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
South Army Street - Al-Zahra Hospital - Operating Room of Tabriz, East Azerbaijan Province
City
Tabriz
Province
East Azarbaijan
Postal code
5138663134
Phone
+98 41 3476 7121
Fax
+98 41 3334 1994
Email
Drtabatabaeigyn@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Doctor fateme tabatabaei
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
South Army Street - Al-Zahra Hospital - Operating

Room of Tabriz, East Azerbaijan Province

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Phone

+98 41 3476 7121

Fax

+98 41 3334 1994

Email

Drtabatabaeigyn@gmail.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 data is potentially shareable after unidentified individuals

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academia and people in industry

Under which criteria data/document could be used

There are no specific restrictions on the use of data or documentation

From where data/document is obtainable

Dr.fateme tabatabaei Drtabatabaeigyn@gmail.com

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

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

Comments