Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Comparing Spinal and General Anesthesia in terms of Postoperative Pain inPatients Undergoing Hysterectomy

Protocol summary

Study aim
The comparison of spinal anesthesia with general anesthesia on the postoperative pain after hysterectomy in patients

Design
This study recruited 40 candidates of abdominal hysterectomy with American Society of Anesthesiologists (ASA) I and II.All the patients were briefed on the pain assessment scale the day before the surgery, randomly divided into two groups of GA and SA and underwent abdominal hysterectomy using the same technique. Postoperative pain was then recorded upon admission to postanesthesia care unit (PACU)and six and twelve hours later

Settings and conduct
Patients undergoing hysterectomy in Semnan Amir Hospital. Patients will be provided with adequate explanations about each procedure and study method before inclusion. Though, they will not know on which procedure they have undergone.

Participants/Inclusion and exclusion criteria
Inclusion Criteria American Society of Anesthesiologists (ASA) I and II class Candidate for hysterectomy Exclusion Criteria Prefer a specific method of anesthesia Psychiatric diseases under medical treatment Patients with chronic or acute pain Anatomical disorder that requires a specific anesthetic method

Intervention groups
Two groups of 20 people included the general anesthesia (GA) and spinal anesthesia(SA)

Main outcome variables
Pain control

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171228038117N2**
Registration date: **2018-02-11, 1396/11/22**
Registration timing: **retrospective**

Last update: **2018-02-11, 1396/11/22**
Update count: **0**

Registration date
2018-02-11, 1396/11/22

Registrant information

Name
Babak Hosseinzadeh zorofchi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-11-21, 1395/09/01

Expected recruitment end date
2017-11-22, 1396/09/01

Actual recruitment start date
2016-12-21, 1395/10/01

Actual recruitment end date
2017-11-01, 1396/08/10

Trial completion date
empty

Scientific title
Comparing Spinal and General Anesthesia in terms of Postoperative Pain inPatients Undergoing Hysterectomy

Public title
Comparing Spinal and General Anesthesia in terms of Postoperative Pain inPatients Undergoing Hysterectomy

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
American Society of Anesthesiologists (ASA) I and II class Candidate for hysterectomy
Exclusion criteria:
Prefer a specific method of anesthesia Psychiatric diseases under medical treatment Patients with chronic or acute pain An anatomical disorder that requires a specific anesthetic method
Age
From **20 years** old to **70 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **50**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants were unaware of the type of anesthesia
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Basij Ave, Semnan Town
City
Semnan
Province
Semnan
Postal code
3517816615
Approval date
2015-11-23, 1394/09/02
Ethics committee reference number
IR.SEMUMS.REC.1394.92

Health conditions studied

1

Description of health condition studied
Post Hysterectomy pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post operative pain
Timepoint
After 30 min
Method of measurement
visual analogue scale (VAS)

Secondary outcomes

1

Description
Nausea
Timepoint
0, 6 and 12 h after the operation
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Vometing
Timepoint
0, 6 and 12 h after the operation
Method of measurement
Visual Analogue Scale (VAS)

Intervention groups

1

Description
Intervention group: After anesthetic monitoring including pulse oximetry, ECG and blood pressure monitoring, premedication was administered by injecting benzodiazepine (intravenous midazolam, 2 mg) and a synthetic narcotic (intravenous fentanyl, 1 mg/kg body weight). GA was induced by injecting intravenous thiopental sodium 5 mg/kg bw, and the muscle relaxant, Atracurium, 0.5 mg/kg bw. After endotracheal intubation, inhalation anesthetic(including equal proportions of oxygen and Nitrous oxide, 4 L/min) and evaporation anesthetic (halogenated anesthetic: Isoflurane 1.2%, 1 MAC) were administered to maintainanesthesia and patients underwent mechanical ventilation using anesthesia ventilators.The patient was extubated at the end of the operation after discontinuing anesthetics and reversing the effects of the muscle relaxants using

anticholineste rasessuch asneostigmine 40-70 µg/kg bw and anticholinergicssuch asintramuscular atropine 15µg/kg b w. They were then transferred to PACU (recovery room).

Category

Treatment - Drugs

2

Description

Control group: After anesthetic monitoring of the patient, including pulse oximetry, ECG and blood pressure monitoring, minimal 500 cc crytalloids serum was intravenously administered to prevent hypotension secondary to SA. After placing the patient in a seated position and using povidone-iodine solution for sterilizing the site of lumbar puncture, the L4/L5intervertebral space was identified. A cutting-tipped 25-gauge (orange) spinal needle was inserted into the intrathecal area, and the accuracy of the technique was ensured by the appearance of cerebrospinal fluid. A total of 3 cc hyperbaric bupivacaine solution 0.5%was then injected into the subarachnoid space and the patient was placed in supine position. After stabilizing SA, the position was adjusted so as to allow the local anesthetic to move toward the T8 area. A needle or alcohol-soaked cotton was used to identify the anesthetic area and the operation began after this area was stabilized. In case of agitation during operation, 1-2 mg of intravenous midazolam was administered, and the patient was transferred to PACU after the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amir Hospital

Full name of responsible person
Babak Hoseinzadeh

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Basij Ave, Semnan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Deputy Research and Technology

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Babak Hoseinzadeh zorofchi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Not applicable