

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparing Spinal and General Anesthesia in terms of Postoperative Pain in Patients 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)

Phone

+98 23 3343 7838

Email address

babak.hoseinzadeh@semums.ac.ir

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 in Patients Undergoing Hysterectomy

Public title

Comparing Spinal and General Anesthesia in terms of Postoperative Pain in Patients 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

Vomiting

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 maintain anesthesia 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

Street address

Basij Ave, Semnan

City

Semnan

Province

Semnan

Postal code

3517816615

Phone

+98 23 3334 7834

Email

babakhz.anesthesia@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Deputy Research and Technology

Street address

Basij Ave,Semnan

City

Semnan

Province

Semnan

Postal code

3517816615

Phone

+98 23 3343 7834

Email

babakhz.anesthesia@gmail.com

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

Street address

Department of Anesthesiology,Kosar Hospital,Semnan University of Medical Sciences,Semnan

City

Semnan

Province

Semnan

Postal code

3517816615

Phone

+98 23 3343 7838

Fax

Email

babak.hoseinzadeh@semums.ac.ir

Person responsible for scientific 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

Street address

Department of Anesthesiology, Kosar Hospital, Semnan University of Medical Sciences, Semnan

City

Semnan

Province

Semnan

Postal code

3517816615

Phone

+98 23 3343 7838

Fax**Email**

babak.hoseinzadeh@semums.ac.ir

Person responsible for updating data

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

Street address

Department of Anesthesiology, Kosar Hospital, Semnan University of Medical Sciences, Semnan

City

Semnan

Province

Semnan

Postal code

3517816615

Phone

+98 23 3343 7838

Fax**Email**

babak.hoseinzadeh@semums.ac.ir

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