Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jul 2026

Comparative Evaluation of intravenous Propofol and Midazolam on sedation and nausea & vomiting during spinal anesthesia in cesarean section

Protocol summary

Study aim

Comparative Evaluation of intravenous Propofol and Midazolam on sedation and nausea & vomiting during spinal anesthesia in cesarean section

Design

102 Pregnant women aged 18-46 years undergoing cesarean section undergoing spinal anesthesia will be in double blind randomized clinical trial. in one of the two intravenous administration of 0.2 mg/kg Propofol and 0.02 mg/kg Midazolam.

Settings and conduct

102 Pregnant women aged 18-46 years undergoing cesarean section undergoing spinal anesthesia who will be referred to the Besat Hospital of Hamadan during the study period, will be randomly assigned to randomized allocation blocks by random sampling. In order to prevent the medication being detectable for patients and investigators, they are prepared and injected into syringes of the same size and shape.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18-45 aged pregnant women for C/S; ASA CLASS 1, 2; Satisfaction to participate in the project; Pregnant women who underwent cesarean section under spinal anesthesia. Exclusion Criteria: sensitivity to medications used; Patients who have failed spinal anesthesia and undergo general anesthesia; Lung disease, heart disease, asthma, fever, hypertension, preeclampsia and eclampsia, cardiac arrhythmia; Emergency Cesarean; Eclampsia and Preeclampsia; Multiple pregnancy; Spinal anesthesia contraindications (high ICP, hypovolemia, anemia, coagulation disorders, etc.); History of allergy to eggs, soy, midazolam and propofol; Use of antiemetic drugs

Intervention groups

Intervention group 1: The amount of 0.2 mg/kg Propofol intravenously after spinal anesthesia by an anesthesiologist injected intravenously. 2 intervention groups: the amount of 0.02 mg/kg Midazolam after spinal anesthesia by an anesthesiologist injected intravenously.

Main outcome variables

Sedation score, time to start sedation and duration of sedation, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N21**
Registration date: **2019-11-14, 1398/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-14, 1398/08/23**
Update count: **0**

Registration date

2019-11-14, 1398/08/23

Registrant information

Name

Nahid Manuchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-22, 1398/07/30

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of intravenous Propofol and Midazolam on sedation and nausea & vomiting during spinal anesthesia in cesarean section

Public title

Evaluation of intravenous Propofol and Midazolam on sedation during spinal anesthesia in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-45 aged pregnant women for C/S ASA CLASS 1, 2 Satisfaction to participate in the project Pregnant women who underwent cesarean section under spinal anesthesia

Exclusion criteria:

sensitivity to medications used Patients who have failed spinal anesthesia and undergo general anesthesia Lung disease, heart disease, asthma, fever, hypertension, preeclampsia and eclampsia, cardiac arrhythmia Emergency Cesarean Eclampsia and Preeclampsia Multiple pregnancy Spinal anesthesia contraindications (high ICP, hypovolemia, anemia, coagulation disorders, etc.) History of allergy to eggs, soy, midazolam and propofol Use of antiemetic drugs

Age

From **18 years** old to **46 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

We write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table.With each of the qualified patients, one of the papers is taken out randomly and, According to the text, the patient is given one of two groups: A (Propofol) and B (Midazolam). Then, for four subsequent patients, the paper is returned to the bag again, and this process is repeated until the end of the sample volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

In both groups A and B, medications after spinal anesthesia one of two drugs (Propofol or Midazolam) will be prescribed.In order to prevent the medication being detectable for patients and investigators, they are prepared and injected into syringes of the same size and shape and on the adhesives A and B by the anesthetist. Since drugs are prescribed by an anesthetist, the clinician will not be aware of the type of prescribed medication that will measure and record the outcome of 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 Hamadan University of Medical Sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.UMSHA.REC.1398.431

Health conditions studied

1

Description of health condition studied

sedation and nausea & vomiting during spinal anesthesia in cesarean section

ICD-10 code

T88.52

ICD-10 code description

Failed moderate sedation during procedure

Primary outcomes

1

Description

sedation

Timepoint

We record ramsy sedation score in 24 hours after

surgery.
Method of measurement
Ramsy sedation score

2

Description
Nausea & vomiting
Timepoint
After surgery
Method of measurement
Observation

Secondary outcomes

1

Description
Systolic and Diastolic Blood Pressure
Timepoint
Every 5 minutes (from drug administration until end of surgery)
Method of measurement
Non-invasive automatic barometric device

2

Description
Heart Rate
Timepoint
Every 5 minutes (from drug administration until end of surgery)
Method of measurement
Using a pulse oximeter

Intervention groups

1

Description
Intervention group: : The amount of 0.2 mg/kg Propofol 1%(10mg/ml and made by B.BRAUN company in Germany), is injected intravenously after spinal anesthesia by anesthesiologist.
Category
Treatment - Drugs

2

Description
Intervention group: The amount of 0.02 mg/kg Midazolam(1mg/ml and made by Caspian pharmaceutical company in Iran), is injected intravenously after spinal anesthesia by anesthesiologist.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences
Street address
Fatemieh Hospital, Pasdaran Street
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hp.fatemieh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Dr. Saeed Bashirian
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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
Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person
Nahid Manouchehrian

Position
Associate professor of Hamadan University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Position
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Person responsible for updating data

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