Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

The effect of subhypnoyic doses of propofol and midazolam to prevent nausea and vomiting during spinal anesthesia for Elective caesarean section

Protocol summary

Summary

Nausea and vomiting during spinal anesthesia for cesarean section is a minor side effect, but can cause patients discomfort and lead to major complication that may cause long time patient recovery and hospitalization. This study is intended to compare the preventive and therapeutic effects of subhypnotic doses of midazolam and propofol on the incidence and severity of intraoperative nausea and vomiting during elective cesarean section under spinal anesthesia. After delivery, most of the paturients under cesarean with spinal anesthesia, require sedation, so in addition to reducing nausea and vomiting, we can also reach to this purpose with administration of these drugs. In this randomized, double-blinded, placebo-controlled study, 90 ASA physical status I and II, parturients, undergoing spinal anesthesia for elective cesarean section are randomly allocated to one of three groups to receive placebo (saline n=30), propofol (20 mg bolus and 1.0 mg/kg/h, n=30) and midazolam (1 mg bolus and 1.0 mg/ h , n=30) at subhypnotic doses intravenously (IV) immediately after clamping of the umbilical cord. A person who is blinded to the drugs, evaluate the intensity of nausea and vomiting and sedation via the Bellvile score system and modified Ramsy sedation scoring respectively. Blood pressures are monitoredand recorded. All data and also total ephedrine consumption will be recorded and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120810765N1**
Registration date: **2013-08-06, 1392/05/15**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2013-08-06, 1392/05/15

Registrant information

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1553 9161

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rasoolis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Women's Reproductive Health Research Center, Tabriz University of Medical Sciences

Expected recruitment start date

2011-03-20, 1389/12/29

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of subhypnoyic doses of propofol and midazolam to prevent nausea and vomiting during spinal anesthesia for Elective caesarean section

Public title

effect of low dose propofol and midazolam to prevent nausea and vomiting during caesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
]Inclusion criteria:Elective cesarean, phisical status of class ASA 1 and 2, age 20-30 years Exclusion criteria: Gastrointestinal disease, history of management with anti emetic drugs in the past 24 h, patients who spinal anesthesia has cnterindication

Age
From **20 years** old to **30 years** old

Gender
Female

Phase
0

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Vice chancellor for research, Tabriz University of Medical Sciences

Street address
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah square, Tabriz

City
Tabriz

Postal code
5138665793

Approval date
2007-08-01, 1386/05/10

Ethics committee reference number
8662

Health conditions studied

1

Description of health condition studied
nausea and vomiting during cesarean section under spinal anesthesia

ICD-10 code
O74.6

ICD-10 code description
Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description
nausea and vomiting

Timepoint
after spinal anesthesia until 6 h

Method of measurement
the intencity of nausea and vomiting with Bellville score

Secondary outcomes

1

Description
blood pressure

Timepoint
the baseline of BP, after spinal anesthesia every 2 minute until 15 min, then every 5 min until the end of operation

Method of measurement
noninvasive by new tech monitoring set

2

Description
Sedation

Timepoint
In the end of operation

Method of measurement
With using of Modified Ramcy sedation scoring

3

Description
Total ephedrine consumption

Timepoint
In the end of operation

Method of measurement
Ephedrine consumption (mg)

Intervention groups

1

Description
In group 1 or placebo(Control) postdelivery, first normal saline iv injected, then infusion of NNormal salin establish until the end of surgery.

Category
Treatment - Drugs

2

Description
In group 2 or Intervention post delivery, first propofol 20 mg intravenous injected, then infusion of propofol 1 mg/kg/h established until the end of surgery.
Category
Treatment - Drugs

3

Description
In group 3 or Midazolam post delivery, Midazolam 1 mg bulos intravenous injected, then infusion of Midazolam 1 mg/kg/h established until the end of surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al Zahra Hospital, Operation Room and cesarean setting
Full name of responsible person
Dr Sousan Rasooli
Street address
Tabriz, Artesh Jonoubi Ave, Al Zahra hospital, Operating room, Dr. Simin Atashkhoyi
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Elahe Olade Saheb Madarek
Street address
Al Zahra hospital, south Artesh ave,
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Women's Reproductive Health Research Center, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Sousan Rasooli
Position
Associate Professor, Specialist in Anesthesiology
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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty