# 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)

**Phone**

+98 41 1553 9161

**Email address**

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**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
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## 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*