# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

03 Jul 2026

## Comparison the effect of intravenous midazolam and ondansetron on nausea and vomiting in cesarean sections with spinal anesthesia

## Protocol summary

**Summary**

The aim of the present study was to compare the efficacy of using intravenous midazolam, ondansetron, and midazolam in combination with ondansetron for the prevention of nausea and vomiting during and after cesarean under spinal anesthesia. This prospective and randomized double-blind study was conducted on 126 pregnant women undergoing cesarean section(3 groups , each group contained 42 patients) with spinal anesthesia aged between 20 and 40 years after the procedure will confirm by Deputy of Research and Ethics and informed consent was taken from the subjects. Inclusion criteria will be pregnant women aged between 20 and 40 years old; ASA class 1 and 2; cesarean with spinal anesthesia.Exclusion criteria will be patients with a history of gastrointestinal disease; smokers; Motion sickness; Allergies to medicines; Previous history of nausea and vomiting during anesthesia; Preeclampsia, Eclampsia; patients who have used anti-nausea drug in the past 24 hours.For first group Midazolam (Tehran Chemie) (2mg),second group Ondansetron (Tehran Chemie) (4mg) and for third group combination of them will be prepared and after closing cord randomly injected. Patients will be monitored through non-invasive blood pressure, electrocardiogram and pulse oximetry. All patients will be received 15 ml/kg ringer lactate before any intervention. Spinal anesthesia will be done in sitting position with a 25-gauge Whitacare needle (Exel), using a midline approach at L4-5 interspace. Once free flow of CSF had been recognized, 12.5 mg of 0.5% bupivacaine (AstraZeneca) will be injected. The incidence of nausea and vomiting during and after cesarean in the recovery room will be examined and recorded. The patients' blood pressure will be measured every 3 minutes.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016073027677N2**
Registration date: **2016-10-19, 1395/07/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2016-10-19, 1395/07/28

**Registrant information**

**Name**
Shahryar Sane
**Name of organization / entity**
Urmia University of Medical Sciences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

Investigator

**Expected recruitment start date**

2015-10-24, 1394/08/02

**Expected recruitment end date**

2016-03-18, 1394/12/28

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of intravenous midazolam and ondansetron on nausea and vomiting in cesarean

sections with spinal anesthesia

**Public title**
Clinical trial effect of midazolam and ondansetron on nausea and vomiting in parturient under cesarean with spinal anesthesia
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
Inclusion criteria: Pregnant women aged between 20 and 40 years old; american society of anesthesiologists class 1 and 2; cesarean with spinal anesthesia Exclusion criteria: Patients with a history of gastrointestinal disease; smokers; Motion sickness; Allergies to medicines; Previous history of nausea and vomiting during anesthesia; Preeclampsia, Eclampsia; patients who have used anti-nausea drug in the past 24 hours.
**Age**
From **20 years** old to **40 years** old
**Gender**
Female

**Phase**
2-3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **126**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Midazolam (Tehran Chemie) (2mg), Ondansetron (Tehran Chemie) (4mg) and combination of them will be prepared as a syringe containing a solution of 5ml and 42 envelopes containing midazolam, 42 envelopes containing ondansetron and 42 envelopes containing a combination of the two will be prepared and randomly placed in a way that the kind of medicine inside envelopes has been written on white paper. The intervening person will inject the packed drug to the patient after closing the cord based on the random numbers table.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Urmia University of Medical Sciences
**Street address**
Emergent Street, Resalat Avenue
**City**
Urmia
**Postal code**
5714783734
**Approval date**
2015-09-11, 1394/06/20
**Ethics committee reference number**
ir.umsu.rec.1394.272

## Health conditions studied

### 1

**Description of health condition studied**
nausea and vomiying in cesarean
**ICD-10 code**
O21
**ICD-10 code description**
Vomiting of pregnancy, unspecified

## Primary outcomes

### 1

**Description**
nausea and vomiting
**Timepoint**
during and after surgery in recovery
**Method of measurement**
patient observation

## Secondary outcomes

### 1

**Description**
blood pressure
**Timepoint**
During operation every 3 minutes after drug injection
**Method of measurement**
none invasive blood pressure

### 2

**Description**
Pulse rate
**Timepoint**
During operation every 3 minutes after drug injection
**Method of measurement**
Electrocardiogram

## Intervention groups

### 1

**Description**
Intervention group 2: Midazolam (Tehran Chemie) (2mg) will be prepared in 5 cc syringes and after closing cord randomly injected.

**Category**
Prevention

**2**

**Description**
Intervention group 3:Midazolam (2mg) and Ondansetron (Tehran Chemie) (4mg) will be prepared in 5 cc syringes and after closing cord randomly injected.
**Category**
Prevention

**3**

**Description**
Intervention group 2: Ondansetron (Tehran Chemie) (4mg) will be prepared in 5 cc syringes and after closing cord randomly injected.
**Category**
Prevention

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Motahhari Hospital
**Full name of responsible person**
Shahryar Sane
**Street address**
Kashani Avenue
**City**
Urmia

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Urmia University of Medical Sciences
**Full name of responsible person**
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**Street address**
Emergent Street, Resalat avenue, Urmia
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Urmia
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Urmia 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**
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## Person responsible for scientific inquiries

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## 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*