

# 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)

##### Phone

+98 44 3223 4897

##### Email address

sane.sh@umsu.ac.ir

#### 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 vomiting 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

non-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**

Shahryar Sane

**Street address**

Emergent Street, Resalat avenue, Urmia

**City**

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****Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Shahryar Sane

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Anesthesiology department

**City**

Urmia

**Postal code**

5714783734

**Phone**

+98 44 3222 4777

**Fax**

+98 44 3346 8967

**Email**

sane.sh@umsu.ac.ir; shahryarsane@yahoo.com;

dr.sh.sane@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Shahryar Sane

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Emergent Street, Resalat Avenue

**City**

Urmia

**Postal code**

5715781351

**Phone**

+98 44 3222 4777

**Fax**

+98 44 3346 8967

**Email**

sane.sh@umsu.ac.ir; shahryarsane@yahoo.com;

dr.sh.sane@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Urmia University of Medical Sciences

**Full name of responsible person**

Shahryar Sane

**Position**

Assistant professor

**Other areas of specialty/work**

**Street address**

Emergent Street, Resalat avenue, Urmia

**City**

Urmia

**Postal code**

5714783734

**Phone**

+98 44 3222 4777

**Fax**

+98 44 3346 8967

**Email**

sane.sh@umsu.ac.ir; shahryarsane@yahoo.com;  
dr.sh.sane@gmail.com

**Web page address**

## 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*