

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison the effect of intravenous ondansetron and sub-hypnotic propofol dose on pruritus after intrathecal opioid in patient with elective cesarean surgery

Protocol summary

Summary

The aim of this study was to compare the effect of intravenous ondansetron and sub-hypnotic dose of propofol in control and treatment of intrathecal fentanyl induced pruritus in cesarean surgery. Inclusion criteria: 20 to 40 years old; patient with class I and II American society of Anesthesiologists; cesarean surgery with spinal anesthesia. Exclusion criteria: any complaints of pruritus before surgery; start pruritus before closing cord; allergy to medications; preeclampsia; eclampsia; people who had used anti-nausea drug in the past 24 hours. 90 Patients undergoing spinal anesthesia with 25 µg fentanyl and 10 mg bupivacaine 0.5% will be enrolled to this randomized, prospective study. The women based on random numbers table will be assigned to two groups (45) who received 4 mg ondansetron or 10 mg propofol and then 10 µg/kg/min infused intraoperative after closing the cord. The incidence and intensity of pruritus (Primary outcome), nausea and vomiting (secondary outcome) will be evaluated intraoperative and in the recovery. If the pruritus is on-going, the exact treatment with naloxone will be done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041527677N7**

Registration date: **2017-07-21, 1396/04/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-21, 1396/04/30

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

Vice Chancellor for research of Urmia University of Medical Sciences

Expected recruitment start date

2016-07-27, 1395/05/06

Expected recruitment end date

2017-03-26, 1396/01/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intravenous ondansetron and sub-hypnotic propofol dose on pruritus after intrathecal opioid in patient with elective cesarean surgery

Public title

Clinical trial the effect of intravenous ondansetron and sub-hypnotic propofol dose on pruritus after intrathecal opioid in patient with elective cesarean surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 20 to 40 years old; patient with class I and II American Society of Anesthesiologists; cesarean surgery with spinal anesthesia
Exclusion criteria: any complaints of pruritus before surgery; start pruritus before closing cord; allergy to medications; preeclampsia; eclampsia; people who had 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: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Patients will be divided into two groups by random number 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, Ershad Avenue

City

Urmia

Postal code

5714783734

Approval date

2016-07-27, 1395/05/06

Ethics committee reference number

171.IR.UMSU.REC.13950299

Health conditions studied**1****Description of health condition studied**

opioid induced pruritus

ICD-10 code

L29.9

ICD-10 code description

Pruritus, unspecified

2**Description of health condition studied**

nausea and vomiting

ICD-10 code

O21.9

ICD-10 code description

Vomiting of pregnancy, unspecified

Primary outcomes**1****Description**

Pruritus

Timepoint

During the surgery and recovery

Method of measurement

visual analog scale

Secondary outcomes**1****Description**

Nausea and vomiting

Timepoint

During the surgery and recovery

Method of measurement

Has- does not have

Intervention groups**1****Description**

Intervention group 1: Immediately after clamping the umbilical cord for first study group ondansetron 4 mg (Exir Company) by intravenous will be injected.

Category

Treatment - Drugs

2**Description**

Intervention group 2: Immediately after clamping the umbilical cord for second study group 10 mg propofol (Fresenius Kabi Company) and then 10 µg/kg/min will be infused intraoperative.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Kosar operating room, Motahhari Hospital

Full name of responsible person

Shahryar Sane

Street address

Kashani Avenue

City

Urmia

Fax

+98 443348967

Email

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

dr.sh.sane@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of 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

Vice Chancellor for research of 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**

Department of Anesthesiology, Motahhari Hospital,
Kashani Avenue

City

Urmia

Postal code

5714615463

Phone

+98 44 3222 4777

**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 3223 4897

Fax**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

City

Urmia

Postal code

5714783734

Phone

+98 44 3223 4897

Fax**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