Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 America 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

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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 America 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 commitee 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 (Fresnius 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

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
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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
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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