Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effect of intravenous Granisetron and placebo on pruritus after intrathecal opioid in cesarean section with spinal anesthesia

Protocol summary

Summary

Abstract Background and purpose: Fentanyl is commonly used for spinal analgesia during labor but it is associated with a high incidence of pruritus. This randomized, double-blind, placebo-controlled study was performed to evaluate the effect of prophylactic Granisetron on the incidence and severity of pruritus among parturients receiving intrathecal fentanyl in cesarean section surgery. Materials and methods: 136 ASA I or II women undergoing elective caesarean section received spinal anesthesia with 0.5% hyperbaric bupivacaine 10 mg, fentanyl 25 µg. After delivery of the baby and clamping of the umbilical cord, they were randomized to receive Granisetron 1mg i.v. (group G) or saline 0.9 % (group S).Inclusion criteria were not a history of gastrointestinal disease؛ allergies to medications؛ pre-eclampsia and eclampsia was taken into account. Exclusion criteria was people who have used anti-nausea drug in the last 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016043027677N1**
Registration date: **2016-06-20, 1395/03/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-20, 1395/03/31

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

2015-09-23, 1394/07/01

Expected recruitment end date

2016-01-21, 1394/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of intravenous Granisetron and placebo on pruritus after intrathecal opioid in cesarean section with spinal anesthesia

Public title

Effect of Granisetron on pruritus

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were not a history of gastrointestinal disease؛ allergies to medications؛ pre-eclampsia؛ eclampsia was taken into account.Exclusion criteria was people who have used anti-nausea drug in the last 24 hours.

Age

From **76 years** old to **96 years** old

Gender

Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **136**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
2cc syringe was used for both groups. Syringe containing the drug and placebo groups A and B are already prepared by someone else, and is tagged that 68 syringe containing drug and 68 syringes containing placebo and after insertion into the box and randomized syringe with any label bring out of the box and was injected to the patients which was achieved without researcher and after completing the questionnaire was informed to the researcher.

Secondary Ids

1

Registry name
none
Secondary trial Id
none
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia University of Medical Sciences
Street address
Jahad Avenue
City
Urrmia
Postal code
5714783734
Approval date
2015-09-09, 1394/06/18
Ethics committee reference number
ir.umsu.rec.1394.190

2

Ethics committee
Name of ethics committee
Urrmia Medical University
Street address
Jahad Avenue
City
Urrmia
Postal code
5714783734
Approval date
2015-09-09, 1394/06/18
Ethics committee reference number
Ir.umsu.rec.1394.190

Health conditions studied

1

Description of health condition studied
opioid induced pruritus
ICD-10 code
L29.9
ICD-10 code description
Itch NOS

Primary outcomes

1

Description
Pruritus
Timepoint
During the surgery and ricovery
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Nausea and vomiting
Timepoint
During surgery and recovery room
Method of measurement
Has- does not have

Intervention groups

1

Description
Immediately after clamping the umbilical cord for study group granisetron (pharmaceutical company Caspian) 1 mg by intravenous injected
Category
Treatment - Drugs

2

Description
immediately after clamping the umbilical cord in the same volume of saline in the control group were injected intravenously
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Hospital
Full name of responsible person
Shahryar Sane,Assistant Professor, Anesthesiologist
Street address
Kashani Avenue
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
piivate
Full name of responsible person
Shahryar Sane
Street address
Ershad avenue, Imam Khomeini Hospital, Dipartment of Anesthesia
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
piivate
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, anesthesiologist
Other areas of specialty/work
Street address
Jahad Avenue
City
Urmia
Postal code
8135157157
Phone
+98 44 3193 7000
Fax
+98 443348967
Email
sane.sh@umsu.ac.ir; shahryarsane@yahoo.com; dr.sh.sane@gmail.com
Web page address
www.umsu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Shahryar Sane
Position
Anesthesiologist
Other areas of specialty/work
Street address
Ershad Avenue, Emam Khomeini Haspital, Department of Anesthesiology
City
Urmia
Postal code
8135157157
Phone
+98 44 3346 8967
Fax
+98 443348967
Email
sane.sh@umsu.ac.ir; shahryarsane@yahoo.comdr.sh.sane@gmail.com
Web page address
www.umsu.ac.ir

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, anesthesiologist
Other areas of specialty/work
Street address
Emam Khomeini Hospital, Department of Anesthesilogy
City
urmia
Postal code
8135157157
Phone
+98 44 3346 8967
Fax
+98 44 3346 8967

Email
sane.sh@umsu.ac.ir;
shahryarsane@yahoo.comdr.sh.sane@gmail.com
Web page address
www.umsu.ac.i

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