

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
lr.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 recovery
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

private

Full name of responsible person

Shahryar Sane

Street address

Ershad avenue, Imam Khomeini Hospital, Department 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

private

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, Imam Khomeini Hospital, Department of Anesthesiology

City

Urmia

Postal code

8135157157

Phone

+98 44 3346 8967

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 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 Anesthesiology

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