Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of intravenous ondansetron on hypotension during cesarean section

Protocol summary

Summary

After approval of research board of Emam Khomeini hospital and ethics committee of Urmia University Of Medical Sciences, with the aim of evaluation of intravenous ondansetron effect on hypotension during cesarean section, a randomized double-blind clinical trial will be conducted. After obtaining informed written consent 70 parturients aged at 20-40 years old with American Society of Anesthesiologists (ASA) class I-II scheduled for the elective cesarean section with spinal anesthesia will be asked to participate in the study. The patients with the history of hypertension, antihypertension drugs consumption, gastrointestinal diseases, motion sickness, allergy to ondansetron, glaucoma, preeclampsia, eclampsia, psychotic disorders and antiemetic drugs use during last 24 hours will be excluded from the study. Using random allocation software, the patients will be divided into study (O) and control (S) groups with equal numbers. In operation room, standard monitoring including noninvasive blood pressure, pulse oximetry and EKG will be attached. 5 minutes before spinal anesthesia, study and control group patients will receive 6 milligram intravenous ondansetron and normal saline solution with equal volumes respectively The patients will receive 5 ml/Kg Ringer solution intravenously and then spinal anesthesia using 12.5 mg hyperbaric bupivacaine will be induced at sitting position and at L3-L4 intervertebral level. After injecting the local anesthetic in subarachnoid space, the patient will be turned back to supine position and the operating table will be tilted 10-15 degrees to prevent aortocaval compression induced hypotension. Oxygen will be administered to the patients during surgery using face- mask. Blood pressures will be measured and recorded at minutes, 0,3,6,9,10,15,20,25,30 and 5-10 milligram intravenous ephedrine will be administered if systolic pressure decreases more than 25 percent of basic systolic or under 100 mm Hg. Mean values of blood pressure, heart rate and also nausea, vomiting and shivering during surgery and stay at recovery unit will be recorded and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017033025600N3**
Registration date: **2017-04-15, 1396/01/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-15, 1396/01/26

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of research, Urmia University Of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of intravenous ondansetron on hypotension during cesarean section

Public title
Effect of intravenous ondansetron on arterial blood pressure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Parturients aged at 20-40 years old with American Society of Anesthesiologists (ASA) class I-II scheduled for the elective cesarean section with spinal anesthesia Exclusion criteria: History of hypertension; antihypertension drugs consumption; gastrointestinal diseases; motion sickness; allergy to ondansetron; glaucoma; preeclampsia; eclampsia; psychotic disorders and antiemetic drugs use during last 24 hours
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Urmia University Of Medical Sciences
Street address
Urgence street,Resaalat boulevard,
City
Urmia
Postal code
5714783734

Approval date
2016-10-26, 1395/08/05
Ethics committee reference number
IR.umsu.rec.1395.301

Health conditions studied

1

Description of health condition studied
Spinal anesthesia induced hypotension during cesarean section
ICD-10 code
O74.6
ICD-10 code description
Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description
Hypotension during cesarean section
Timepoint
at minutes 0,3,6,10,15,20,25,30
Method of measurement
None invasive blood pressure measuring

Secondary outcomes

1

Description
Nausea during surgery and stay in recovery unit
Timepoint
At any time during surgery and stay in recovery unit
Method of measurement
By asking the patient

2

Description
Vomiting during surgery and stay in recovery unit
Timepoint
At any time during surgery and stay in recovery unit
Method of measurement
By asking the patient

3

Description
Shivering during surgery and stay in recovery unit
Timepoint
At any time during surgery and stay in recovery unit
Method of measurement
By asking the patient

Intervention groups

1

Description
Intravenous administration of 6 milligram ondansetron 5 minutes before spinal anesthesia
Category
Treatment - Drugs

2

Description
Intravenous administration of 5 milliliters of normal saline solution 5 minutes before spinal anesthesia
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari teaching hospital of Urmia
Full name of responsible person
Dr. Shahram Shokohi
Street address
Kashani avenue
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Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor of resrearch, Urmia University Of Medical Sciences
Full name of responsible person
Dr. Iraj Mohebbi
Street address
Urgence avenue, Jahad street, Resalat boulevard
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 of resrearch, 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

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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