Comparison the effect of intravenous midazolam and ondansetron on nausea and vomiting in cesarean sections with spinal anesthesia

Protocol summary

Summary
The aim of the present study was to compare the efficacy of using intravenous midazolam, ondansetron, and midazolam in combination with ondansetron for the prevention of nausea and vomiting during and after cesarean under spinal anesthesia. This prospective and randomized double-blind study was conducted on 126 pregnant women undergoing cesarean section (3 groups, each group contained 42 patients) with spinal anesthesia aged between 20 and 40 years after the procedure will confirm by Deputy of Research and Ethics and informed consent was taken from the subjects. Inclusion criteria will be pregnant women aged between 20 and 40 years old; ASA class 1 and 2; cesarean with spinal anesthesia. Exclusion criteria will be patients with a history of gastrointestinal disease; smokers; Motion sickness; Allergies to medicines; Previous history of nausea and vomiting during anesthesia; Preeclampsia, Eclampsia; patients who have used anti-nausea drug in the past 24 hours. For first group Midazolam (Tehran Chemie) (2mg), second group Ondansetron (Tehran Chemie) (4mg) and for third group combination of them will be prepared and after closing cord randomly injected. Patients will be monitored through non-invasive blood pressure, electrocardiogram and pulse oximetry. All patients will be received 15 ml/kg ringer lactate before any intervention. Spinal anesthesia will be done in sitting position with a 25-gauge Whitacare needle (Exel), using a midline approach at L4-5 interspace. Once free flow of CSF had been recognized, 12.5 mg of 0.5% bupivacaine (AstraZeneca) will be injected. The incidence of nausea and vomiting during and after cesarean in the recovery room will be examined and recorded. The patients’ blood pressure will be measured every 3 minutes.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2016073027677N2
Registration date: 2016-10-19, 1395/07/28
Registration timing: retrospective

Last update:
Update count: 0
Registration date
2016-10-19, 1395/07/28

Registrant information
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Recruitment status
Recruitment complete
Funding source
Investigator

Expected recruitment start date
2015-10-24, 1394/08/02
Expected recruitment end date
2016-03-18, 1394/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of intravenous midazolam and ondansetron on nausea and vomiting in cesarean sections with spinal anesthesia

Public title
Clinical trial effect of midazolam and ondansetron on nausea and vomiting in parturient under cesarean with spinal anesthesia

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: Pregnant women aged between 20 and 40 years old; american society of anesthesiologists class
1 and 2; cesarean with spinal anesthesia Exclusion criteria: Patients with a history of gastrointestinal disease; smokers; Motion sickness; Allergies to medicines; Previous history of nausea and vomiting during anesthesia; Preeclampsia, Eclampsia; patients who have 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: 126

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Midazolam (Tehran Chemie) (2mg), Ondansetron (Tehran Chemie) (4mg) and combination of them will be prepared as a syringe containing a solution of 5ml and 42 envelopes containing midazolam, 42 envelopes containing ondansetron and 42 envelopes containing a combination of the two will be prepared and randomly placed in a way that the kind of medicine inside envelopes has been written on white paper. The intervening person will inject the packed drug to the patient after closing the cord based on the random numbers 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, Resalat Avenue
City
Urmia
Postal code
5714783734
Approval date
2015-09-11, 1394/06/20
Ethics committee reference number
ir.umsu.rec.1394.272

Health conditions studied

1
Description of health condition studied
nausea and vomiting in cesarean
ICD-10 code
O21
ICD-10 code description
Vomiting of pregnancy, unspecified

Primary outcomes

1
Description
nausea and vomiting
Timepoint
during and after surgery in recovery
Method of measurement
patient observation

Secondary outcomes

1
Description
blood pressure
Timepoint
During operation every 3 minutes after drug injection
Method of measurement
none invasive blood pressure

2
Description
Pulse rate
Timepoint
During operation every 3 minutes after drug injection
Method of measurement
Electrocardiogram

Intervention groups

1
Description
Intervention group 2: Midazolam (Tehran Chemie) (2mg) will be prepared in 5 cc syringes and after closing cord randomly injected.
Category
Prevention

2
Description
Intervention group 3: Midazolam (2mg) and Ondansetron (Tehran Chemie) (4mg) will be prepared in 5 cc syringes and after closing cord randomly injected.
Category
Prevention
Description
Intervention group 2: Ondansetron (Tehran Chemie) (4mg) will be prepared in 5 cc syringes and after closing cord randomly injected.

Category
Prevention

Recruitment centers

1
Recruitment center
Name of recruitment center
Motahhari Hospital
Full name of responsible person
Shahryar Sane
Street address
Kashani Avenue
City
Urmia

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Shahryar Sane
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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
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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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dr.sh.sane@gmail.com
Web page address

Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

empty

empty

empty

empty

empty