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.
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
   Non 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
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Street address
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
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
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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