

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison effects of intravenous midazolam and ondansetron on nausea and vomiting after spinal anesthesia for cesarean section

Protocol summary

Summary

The overall goal: to determine and Comparison effects of intravenous midazolam and ondansetron on nausea and vomiting after spinal anesthesia for cesarean section. Study design: Randomized, single-blind, No placebo-controlled. The study population: consists of patients who were referred for elective cesarean section Fatemieh Hospital operating room in Hamadan City Inclusion criteria: Age 18-40 years and undergoing cesarean section; physical status class I or II in accordance with anesthesia; Term pregnancy (gestational age 36-40 weeks); Singleton pregnancy. Exclusion criteria: High-risk pregnancy; A history of liver, Mental, renal, gastrointestinal disorders and motion sickness; history of hyperemesis gravidarum; The patients who received antiemetics during previous 24 hours; history of drug addiction; history of postoperative nausea and vomiting; Patients with spinal anesthesia ban. The sample size: In this study, 40 patients in each group is examined. Intervention or interventions studied: Patients were randomly divided into two groups A Midazolam 20 µg / kg, Group B ondansetron 4mg divided. Drugs after clamping the umbilical cord is injected intravenously. Primary outcome: Nausea and vomiting will be evaluated using standard 0 to 3 and severity nausea will be evaluated by Visual analogue scale. Secondary outcome: Patients' satisfaction and complications such as Changes in blood pressure and heart rate, arterial oxygen saturation will be reviewed .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021112251N4**

Registration date: **2017-05-27, 1396/03/06**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-27, 1396/03/06

Registrant information

Name

Nasim Alipour

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 918 312 6716

Email address

n.alipour@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Hamadan University of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison effects of intravenous midazolam and ondansetron on nausea and vomiting after spinal anesthesia for cesarean section

Public title

effects of midazolam and ondansetron on nausea and vomiting after spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-40 years and undergoing cesarean section; physical status class I or II in accordance with anesthesia; Term pregnancy (gestational age 36-40 weeks); Singleton pregnancy. Exclusion criteria: High-risk pregnancy; Preeclampsia; A history of liver, Mental, renal, gastrointestinal disorders and motion sickness; history of hyperemesis gravidarum; The patients who received antiemetics during previous 24 hours; history of drug addiction; history of postoperative nausea and vomiting; Patients with spinal anesthesia ban.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization: The patients will be randomly assigned to two groups using Random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor of Research the Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave Hamadan

City

Hamadan

Postal code

6517838695

Approval date

2017-01-14, 1395/10/25

Ethics committee reference number

IR.UMSHA.REC.1395.444

Health conditions studied

1

Description of health condition studied

post spinal nausea and vomiting

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

Nausea and vomiting

Timepoint

Since spinal anesthesia or intravenous of midazolam or ondansetron

Method of measurement

Nausea vomiting scale

2

Description

Nausea intensity

Timepoint

Since spinal anesthesia or intravenous of midazolam or ondansetron

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Hemodynamic instability

Timepoint

during the surgery and recovery

Method of measurement

vital sign monitoring device

2

Description

heart rate

Timepoint

during the surgery and recovery

Method of measurement

vital sign monitoring device

3

Description

arterial blood oxygen saturation

Timepoint

during the surgery and recovery

Method of measurement

vital sign monitoring device

4

Description

Patients' satisfaction

Timepoint

In recovery

Method of measurement

4 point Likert scale. Including low satisfaction, average, good and excellent.

Intervention groups

1

Description

In First group, we will inject 20µg /kg of Midazolam IV. after clamping the umbilical cord.

Category

Prevention

2

Description

In Second group, we will inject 4mg of ondansetron IV. after clamping the umbilical cord.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Zahra Ghasemlo

Street address

Fatemieh hospital, Pasdaran Ave

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City

Hamadan

Grant name

--

Grant code / Reference number

--

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Hamadan 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

Contact

Name of organization / entity

Hospital Fatemieh

Full name of responsible person

Zahra Ghasemlo

Position

Student Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Para Medicine

Full name of responsible person

Nasim Alipour

Position

Master of Critical Care Nurses, Clinical Instructor

Other areas of specialty/work

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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