Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of midazoalm, ondansetron, and a combination for treatment of postoperative nausea and vomiting after spinal anestheisa for cesarean delivery

Protocol summary

Summary

The aim of this double-blinded randomized clinical trial is comparing the efficacy of using intravenous midazoalm, ondansetron, and midazolam in combination with ondansetron for treatment of nausea and vomiting after cesarean delivery in parturient underwent spinal anesthesia. One-hundred thirty two parturients are randomly allocated to one of three group: Group M (n = 44) intravenous midazoalm 30 µg/kg; Group O (n = 44) intravenous ondansetron 8 mg; Group MO (n = 44) intravenous midazoalm 30 µg/kg combined with intravenous ondansetron 8 mg.These drugs is administered after umbilical cord clamping if patients have vomiting or VAS of nausea ≥ 3 until 24 hours postoperatively. All parturients receive 10 ml/kg ringer lactate solution. Then spinal anaesthesia is done in sitting position using 25 G sprotte needle. Participants are including parturients with ASA physical status I-II, scheduled for elective cesarean section, under spinal anaesthesia and exclude with suspicious to bleeding disturbances, atopia, diabetes mellitus, presence of liver or kidney diseases, drugs abuse, complicated pregnancy and preeclampsia. The incidence of nausea and vomiting and nausea scale is evaluated among the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201302405N10**
Registration date: **2012-02-16, 1390/11/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-02-16, 1390/11/27

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2010-10-12, 1389/07/20

Expected recruitment end date

2012-01-27, 1390/11/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of midazoalm, ondansetron, and a combination for treatment of postoperative nausea and vomiting after spinal anestheisa for cesarean delivery

Public title

Comparison of midazoalm, ondansetron, and a combination for treatment of postoperative nausea and vomiting after spinal anestheisa for cesarean delivery

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion Criteria: Parturients; ASA physical status I-II; scheduled for elective cesarean section; using spinal anesthesia; Exclusion Criteria: suspicious to bleeding disturbances; atopia; diabetes mellitus; presence of liver or kidney diseases; drugs abuse; complicated pregnancy; preeclampsia
Age
From **16 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-chancellor for Research, Ethics committee of Isfahan University of Medical Sciences
Street address
Vice-chancellor for Research, Gostaresh Building, Isfahan University of Medical Sciences
City
Isfahan
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
22265

Health conditions studied

1

Description of health condition studied
Complications of anaesthesia during pregnancy
ICD-10 code
O29.8
ICD-10 code description
Other complications of anaesthesia during pregnancy

Primary outcomes

1

Description
Frequency of nausea and vomiting
Timepoint
at recovery, 4, 8, 12 and 24 hours after surgery
Method of measurement
counting

2

Description
nausea intensity
Timepoint
at recovery, 4, 8, 12 and 24 hours after surgery
Method of measurement
Visual Analogous Scale (VAS) and scoring from 0 to 10

Secondary outcomes

1

Description
opioid consumption
Timepoint
at recovery, 4, 8, 12 and 24 hours after surgery.
Method of measurement
in milligramme of opioid

Intervention groups

1

Description
intravenous midazoalm 30 µg/kg. Duration of intervention: single dose in 10 seconds if patients have vomiting or VAS of nausea ≥ 3. Duration of treatment: on demand after umbilical cord clamping, During spinal anaesthesia until 24 hours postoperatively
Category
Treatment - Drugs

2

Description
intravenous ondansetron 8 mg. Duration of intervention: single dose in 10 seconds if patients have vomiting or VAS of nausea ≥ 3. Duration of treatment: on demand after umbilical cord clamping, During spinal anaesthesia until 24 hours postoperatively
Category
Treatment - Drugs

3

Description
intravenous midazoalm 30 µg/kg combined with intravenous ondansetron 8 mg. Duration of intervention:

single dose in 10 seconds if patients have vomiting or VAS of nausea ≥ 3. Duration of treatment: on demand after umbilical cord clamping, During spinal anaesthesia until 24 hours postoperatively

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Medical Center

Full name of responsible person

Dr. Mitra Jabalameli

Street address

Pol fellezi

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr. Payman Adibi

Street address

Vice-chancellor for Research, Gostaresh Building, Isfahan University of Medical Sciences, Hezar Jarib St.

City

Isfahan

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, Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mitra Jabalameli

Position

Specialist and Associate professor of Anaesthesia and intensive care

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