

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Treatment of postoperative nausea and vomiting after spinal anesthesia for cesarean delivery: a randomized comparison of midazolam, ondansetron, and a combination

Protocol summary

Summary

The aim of the present study was to compare efficacy of using intravenous midazolam, 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 parturient were randomly allocated to one of three group: Group M (n = 44) that received intravenous midazolam 30 µg/kg; Group O (n = 44) which received intravenous ondansetron 8 mg and Group MO (n = 44) that received intravenous midazolam 30 µg/kg combined with intravenous ondansetron 8 mg if patients had vomiting or VAS of nausea ≥ 3 during surgery (after umbilical cord clamping) and 24 hours after that. The incidence and severity of vomiting episodes and nausea with visual analogue scale (VAS) > 3 was evaluated at 2hr, 6hr, and 24 hr after injection of study drugs.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201308877N1**
Registration date: **2012-02-05, 1390/11/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-02-05, 1390/11/16

Registrant information

Name

Mohsen Chitsazi

Name of organization / entity

Isfahan University of Medical Sciences

Country

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mch61084@yahoo.com

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2010-12-01, 1389/09/10

Expected recruitment end date

2012-03-29, 1391/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment of postoperative nausea and vomiting after spinal anesthesia for cesarean delivery: a randomized comparison of midazolam, ondansetron, and a combination

Public title

Postoperative nausea and vomiting after cesarean delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with ASA I; age between 18 to 45 years old; scheduled for elective cesarean delivery under spinal anesthesia and signing written informed consent to participate in the present study. Exclusion criteria: patients who had smoking habit; obstetric

complications or any evidence of fetal compromise; patients who had history of motion sickness; previous postoperative emesis; gastrointestinal disease or administration of antiemetic medication in the previous 24 hours; having allergy to the study drugs and any contraindication for spinal anesthesia.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

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**

Isfahan University of Medical Sciences Ethics Committee

Street address

Isfahan

City

Isfahan

Postal code

8199657343

Approval date

2010-12-22, 1389/10/01

Ethics committee reference number

289268

Health conditions studied**1****Description of health condition studied**

Postoperative nausea and vomiting

ICD-10 code

Y48.4

ICD-10 code description

Anaesthetic, unspecified

Primary outcomes**1****Description**

Postoperative nausea and vomiting

Timepoint

Half an hour after Intervention

Method of measurement

Visual analogous scale(VAS)

Secondary outcomes**1****Description**

Sedation

Timepoint

Half, 2,4 and 24 hours after intervention.

Method of measurement

Ramsay sedation scale

Intervention groups**1****Description**

Group MO (n = 44) that received intravenous midazolam 30 µg/kg combined with intravenous ondansetron 8 mg

Category

Treatment - Drugs

2**Description**

Group O (n = 44) which received intravenous ondansetron 8 mg;

Category

Treatment - Drugs

3**Description**

Group M (n = 44) received intravenous midazolam 30 µg/kg.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Beheshti Hospital

Full name of responsible person

Mitra jabalameli md. anesthesiologist

Street address

Ostad Motahari St., Felezi Bridge, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Mr. Moradi

Street address

Isfahan University of Medical Sciences

City

Isfahan

Grant name

Grant code / Reference number

289268

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

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Associate professor

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