Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of intravenous Metoclopramide on postoperative analgesia in cesarean section under spinal anesthesia

Protocol summary

Summary

This study is a randomized, double-blinded clinical trial in Imam Khomeini Teaching Hospital, Sari. Following Ethics Committee approval and complement informed consent, 100 parturient females referred for cesarean section under spinal anesthesia based on American Society of Anesthesiologists (ASA) category in class of I or II, by used closed packages are allocated randomly to one of the two groups of 50. Inclusion criteria including patients aged 20-35 years, and exclusion criteria including indisposition, emergency section, prolonged surgery, smoking and narcotic user and psychiatric disorders. The intervention group is received Metoclopramide as 10 mg per kg Metoclopramide intravenously at the end of surgery. The control group is received Normal Saline intravenously in the same volume of Metoclopramide based on milliliter at the end of surgery. After surgery, PCA pumps (morphine 25 mg, 1 gr Apotel and the rest to a volume of 50 ml saline) is prepared for all patients. Outcome of Pain severity and complications such as nausea and vomiting are evaluated in recovery and at the times of 2, 4, 6, 12, 18, 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031232676N2**
Registration date: **2017-04-19, 1396/01/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-04-19, 1396/01/30

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Mazandaran University of Medical of Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intravenous Metoclopramide on postoperative analgesia in cesarean section under spinal anesthesia

Public title

Effect of Metoclopramide infusion on postoperative analgesia in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Elective cesarean surgery; patients aged 20-35 years; American Society of Anesthesiologists (ASA) class I and II. Exclusion criteria: indisposition; emergency section; prolonged surgery; smoking and narcotic user; psychiatric disorders.

Age
From **20 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of the Mazandaran University of Medical Sciences
Street address
Valiasr bolvard, Sari
City
Sari
Postal code
Approval date
2017-04-04, 1396/01/15
Ethics committee reference number
2351

Health conditions studied

1

Description of health condition studied
caesarean surgery
ICD-10 code
O82.9
ICD-10 code description
Delivery by caesarean section, unspecified

Primary outcomes

1

Description
pain
Timepoint
During 24 hours after the surgry, at time 2, 4, 6, 12, 18, 24
Method of measurement
visual analog scale from 0 (without pain) to 10 (extremely pain)

Secondary outcomes

1

Description
ponv
Timepoint
During 24 hour after the surgery
Method of measurement
Visual Analog Scale

Intervention groups

1

Description
In treatment group, the end of surgery, 10 mg per kg of bolus Metoclopramide injected intravenously.
Category
Treatment - Drugs

2

Description
In control group, we injected bolus dose of Normal Saline intravenously instead of Metoclopramid. (in same volume of Metoclopramide based on milliliter) the end of surgery.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Sara Malekshah
Street address
Imam Khomeini Hospital, Razi street, Sari
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research of Mazandaran University of Medical Sciences
Full name of responsible person
Dr Ahmad Ali Enayati

Street address
Moallem square, Sari
City
Sari
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 Mazandaran 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
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Person responsible for updating data

Contact

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