Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effects of ondansetron and metoclopramide on blood pressure of patients after spinal anesthesia during cesarean section

Protocol summary

Study aim
Comparison of the effects of ondansetron and metoclopramide on blood pressure of patients after spinal anesthesia during cesarean section
Design
Clinical trial without control group, with parallel, double-blind, randomized groups in which 48 patients with a size of 4 blocks will be randomly assigned to two groups.
Settings and conduct
Pregnant women 20-40 years old who are candidates for elective cesarean section referred to the Babol Clerical Training Center are randomly divided into two groups. Intravenous face Intervention group 2: 30 minutes before the start of spinal anesthesia 4 mg of ondansetron (elixir pharmacy) once intravenously
Participants/Inclusion and exclusion criteria
Inclusion Criteria: Pregnant women with a pregnancy over 34 weeks are candidates for elective cesarean section, ASA (American Society Anesthesiology) Class I,II Exclusion criteria: Allergy to ondansetron or metoclopramide, Use of antiemetic in the last 24 hours, Gastrointestinal diseases, Preeclampsia
Intervention groups
Intervention group 1: 30 minutes before the start of spinal anesthesia 10 mg of metoclopramide (Amin Pharmacy) once intravenously Intervention group 2: 30 minutes before the start of spinal anesthesia 4 mg of ondansetron (Exir pharmacy) once intravenously
Main outcome variables
Blood pressure

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190928044907N3**
Registration date: **2021-08-08, 1400/05/17**
Registration timing: **registered_while_recruiting**
Last update: **2021-08-08, 1400/05/17**
Update count: **0**
Registration date
2021-08-08, 1400/05/17

Registrant information
Name
seyed hossein hamidi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3222 3301
Email address
a.hamidi@mubabol.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-08-07, 1400/05/16
Expected recruitment end date
2022-03-21, 1401/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of ondansetron and metoclopramide on blood pressure of patients after spinal anesthesia during cesarean section

Public title
Comparison of the effect of ondansetron with metoclopramide on blood pressure
Purpose
Treatment
Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women with a pregnancy over 34 weeks are candidates for elective cesarean section ASA (American Society Anesthesiology) Class I,II
Exclusion criteria:
Allergy to ondansetron or metoclopramide Use of antiemetic in the last 24 hours Gastrointestinal diseases Preeclampsia

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using permutation blocks with instrument 4. Thus, 4 blocks consist of random combinations of compounds 2 to A (metoclopramide) and 2 to B (ondansetron). Random sequencing of blocks will be done by a statistician.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blind the study, the drugs are diluted with 10 cc of normal saline before injection by a colleague and prepared in coded syringes. As a result, neither patients nor the anesthesiologist will know the type of drug prescribed.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Babol University of Medical Sciences

Street address
Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran

Postal code
4717647745

Approval date
2021-05-15, 1400/02/25

Ethics committee reference number
IR.MUBABOL.REC.1400.148

Health conditions studied

1

Description of health condition studied
Blood pressure

ICD-10 code
074.6

ICD-10 code description
other cpmplications of spinal and epidural anesthesia during labour and delivery

Primary outcomes

1

Description
Blood Pressure

Timepoint
Basic before spinal anesthesia every two minutes to a quarter, then every five minutes until the end of surgery

Method of measurement
In a non-invasive way with the monitoring device of Saadat Company

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 30 minutes before the start of spinal anesthesia 10 mg of metoclopramide (Amin Pharmacy) once intravenously

Category
Treatment - Drugs

2

Description
Intervention group: 30 minutes before the start of spinal anesthesia 4 mg of ondansetron (Exir pharmacy) once intravenously

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Rouhani Hospital

Full name of responsible person
Seyed Hossein Hamidi
Street address
Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
s.hosseinhamidi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3219 7667
Email
rezaghadimi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Seyed Hossein Hamidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
s.hosseinhamidi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Seyed Hossein Hamidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
s.hosseinhamidi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
seyed Hossein Hamidi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work

Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
s.hosseinhamidi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is still no plan for its publish

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available