

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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	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 cpmlications 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 Ids empty	Secondary outcomes 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	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