Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of Prophylactic ondansetron in prevention of maternal hypotension following spinal anesthesia in women undergoing cesarean section

Protocol summary

Study aim

Study of the efficacy of intravenous ondansetron in prevention of hypotension following spinal anesthesia in women undergoing cesarean section

Design

This is a controlled double-blinded clinical trial study will be conducted on 60 women undergoing cesarean section with spinal anesthesia. After coordination and obtaining informed consent, the patients (n=30per group) will be randomly assigned into two groups of intravenous ondansetron (10 mg) or normal saline at the same dose and will be received the medications before spinal anesthesia.

Settings and conduct

From pregnant women candidate for cesarean section with spinal anesthesia referring to Imam Khomeini hospital, Ahvaz, total of 30 patients will be selected and randomly divided into 2 groups. In the first group, ondansetron10 mg will be injected intravenously before spinal anesthesia. In the second group, normal saline 10 mg will be used. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria

- Inclusion criteria: age between 18 to 40 years, Candidate for elective cesarean section, no contraindication for spinal anesthesia, Consent to participate in the study; Exclusion criteria: Hypertension, weight more than 100 kg, motion sickness, cardiovascular disease, liver disease, migraine, allergy to ondansetron medications group, using any medication which effect the blood pressure or heart rate.

Intervention groups

In the first group, ondansetron 10 mg will be injected intravenously before spinal anesthesia. In the second group, normal saline 10 mg will be used as control.

Main outcome variables

All patients will be examined for Hemodynamics change (HR, SBP, DBP) and side-effects after surgery (nausea, vomiting, chills, itching) up to 2 hours after the patient entry to recovery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191015045121N1**
Registration date: **2019-10-26, 1398/08/04**
Registration timing: **prospective**

Last update: **2019-10-26, 1398/08/04**
Update count: **0**

Registration date

2019-10-26, 1398/08/04

Registrant information

Name

Maryam Mofrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3001 3374

Email address

mofrad.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of Prophylactic ondansetron in prevention of maternal hypotension following spinal anesthesia in women undergoing cesarean section

Public title
Effect of ondansetron in prevention of hypotension following spinal anesthesia in cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 40 years Candidate for elective cesarean section no contraindication for spinal anesthesia
Exclusion criteria:
Patients with hypertension Weight more than 100 kg Motion sickness Cardiovascular disease Liver disease Migraine Allergy to ondansetron medications group Using any medication which effect the blood pressure or heart rate
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups of experimental and control. Each patient is given a number from 1 to 60 and assignment of patients into the study groups will be done by table of random numbers.
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention (receiving normal saline orondansetron) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also patients and statistical analyzer will not know about patient grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2019-08-19, 1398/05/28
Ethics committee reference number
IR.AJUMS.REC.1398.415

Health conditions studied

1

Description of health condition studied
Hypotension after cesarean section
ICD-10 code
I95.81
ICD-10 code description
Postprocedural hypotension

Primary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
At the beginning of the study (before the intervention) and then every 5 minutes
Method of measurement
Mercury barometer

2

Description
side-effects after surgery
Timepoint
up to 2 hours after the patient entry to recovery.
Method of measurement
presence of Itching, chills, nausea and vomiting based on direct observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: ondansetron 10 mg (Demitron, Tehran Shimi CO., Iran) will be injected intravenously 5 min before performing spinal anesthesia.
Category
Prevention

2

Description
Control group: normal saline 10 mg will be injected intravenously 5 min before performing spinal anesthesia
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Maryam Mofrad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad Reza Mohtadi
Position
Assistant Professor
Latest degree
Specialist
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Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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