Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

Protocol summary

Study aim

Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

Design

The clinical trial has a control group, with parallel groups, double-blind, approved, phase 2-3 in 180 patients. Randomization is by using https://www.sealedenvelope.com website.

Settings and conduct

Intervention group one: patients will receive Ephedrine 10 mg , during 5 minutes before spinal anesthesia .Intervention group two: patients will receive Ondansetron 8 mg , during 5 minutes before spinal anesthesia. Control group: patients will receive10 cc normal saline as placebo during 5 minutes before spinal anesthesia. Anesthesiologist and surgeon were blinded, Neither the participants nor the investigators involved in data collection and assessing the outcomes are aware of the identity of the target drugs.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 years, Elective cesarean section, ASA classification I-II, Term and singleton pregnancy. Exclusion Criteria: Diabetes, Hypertension , Body mass index 40, Complicated pregnancy such as placenta Previa, preeclampsia, history of Long QT syndrome, history of Electrolyte imbalance, Contraindication to the spinal anesthesia, Failed spinal block or total spinal converted to general anesthesia, history of allergy to or side effects to the study drugs.

Intervention groups

Intervention group one: patients will receive Ephedrine 10 mg , during 5 minutes before spinal anesthesia . Intervention group two: patients will receive Ondansetron 8 mg , during 5 minutes before spinal anesthesia. Control group: patients will receive10 cc normal saline as placebo during 5 minutes before spinal anesthesia.

Main outcome variables

Hemodynamic changes ,nausea and vomiting, motor block duration .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N106**
Registration date: **2021-01-26, 1399/11/07**
Registration timing: **prospective**

Last update: **2021-01-26, 1399/11/07**
Update count: **0**

Registration date

2021-01-26, 1399/11/07

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-02, 1399/11/14

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

Public title
Comparison of the efficacy of prophylactic ondansetron and ephedrine on hypotension associated with spinal anesthesia in cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 years Elective cesarean section ASA classification I-II Term and singleton pregnancy

Exclusion criteria:
DM Hypertensive disorder Body Mass Index 40 Complicated pregnancy such as placenta Previa, preeclampsia History of Long QT syndrome History of Electrolyte imbalance Contraindication to spinal anesthesia Failed spinal block or total spinal converted to general anesthesia History of allergy to or side effects to the study drugs.

Age
From **18 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly divided into three groups of drugs and placebo. Randomization is by using https://www.sealedenvelope.com website.

Blinding (investigator's opinion)
Double blinded

Blinding description
Medications were prepared by an anesthesia nurse who were totally unaware of the nature of the study who is verified the allocation and prepared ondansetron 8 mg with 0.9% saline solution to a total volume of 10 mL or a placebo of 0.9% saline solution 10 mL and ephedrine 10 mg with 0.9% saline solution to a total volume of 10 ml. While anesthesiologist and surgeon were blinded, Neither the participants nor the investigators involved in data collection and assessing the outcomes are aware of the identity of the target drugs. The syringes had no identifying markers indicating group allocation. The nurse injected the contents of the 10-mL syringe intravenously over 60 s, 5 min before the lumbar puncture. The anesthetist is blinded to group allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Province
Fars

Postal code
7134844119

Approval date
2020-12-15, 1399/09/25

Ethics committee reference number
IR .SUMS.MED.REC.1399.471

Health conditions studied

1

Description of health condition studied
cesarean

ICD-10 code
O82

ICD-10 code description
Encounter for cesarean delivery without indication

Primary outcomes

1

Description
Hemodynamic data (SBP, DBP, MAP, HR, and SaO2)

Timepoint
During Operation

Method of measurement
Manitoring

Secondary outcomes

1

Description
Duration of motor block
Timepoint
7 and 15 min after intrathecal injection
Method of measurement
Bromage scale

Intervention groups

1

Description
Intervention group one: patients will receive Ephedrine (Aterop, Belgium) 10 mg , during 5 minutes before spinal anesthesia .
Category
Prevention

2

Description
Intervention group two: patients will receive Ondansetron (Exir, Iran) 8 mg , during 5 minutes before spinal anesthesia.
Category
Prevention

3

Description
Control group: patients will receive10 cc normal saline as placebo during 5 minutes before spinal anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospital
Full name of responsible person
Parnian Baghban
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Sponsors / Funding sources

1

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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
Shiraz 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
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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
Its against our policy.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available