

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the Effect of Ephedrine and Ondansetron on Spinal induced Hypotension Cesarean Section

Protocol summary

2019-10-12, 1398/07/20

Study aim

Comparison of the Effect of Ephedrine and Ondansetron on Prevention of Hypotension after Spinal Anesthesia in Cesarean Section

Design

A randomized, Double-blind, Placebo-controlled Clinical trial of Ephedrine and Ondansetron

Settings and conduct

The study will be conducted in the operating room of Mousavi Hospital in Zanjan. The patient and the clinical evaluator are unaware of the syringe content and patient grouping. And the type of medication prescribed and the patient group selected by the sealed envelope

Participants/Inclusion and exclusion criteria

Age 18-45 years Absence of cardiovascular and renal and hepatic disease No spinal anesthesia contraindications ASA Class I, II

Intervention groups

Group A is a control group that receives 2 ml of distilled water. Group B is the ephedrine group, which receives 2 ml of solution containing 10 mg of the drug. Group C is the ondansetron group that receives 2 ml of solution containing 4 mg of the drug.

Main outcome variables

Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160818029414N5**

Registration date: **2019-10-12, 1398/07/20**

Registration timing: **prospective**

Last update: **2019-10-12, 1398/07/20**

Update count: **0**

Registration date

Registrant information

Name

Vahideh Rashtchi

Name of organization / entity

Zanjan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 341 1683

Email address

rashtchi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-01, 1398/08/10

Expected recruitment end date

2019-12-01, 1398/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Ephedrine and Ondansetron on Spinal induced Hypotension Cesarean Section

Public title

Effect of Ephedrine and Ondansetron on Hypotension after Spinal Anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18-45 year ASA I,II Elective Cesarean section under Spinal Anesthesia

Exclusion criteria:
Patient dissatisfaction Infection at the spinal needle
insertion site High intracranial pressure Coagulation
Disorders A history of allergy to local anesthetics Heart,
kidney, liver disease

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **165**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were randomly assigned to One of three Study
groups using the Sealed Envelope Method

Blinding (investigator's opinion)

Double blinded

Blinding description

The clinical evaluator, who is an Anesthetist present in
the Operating Room, selects one of the three envelopes
in which the letters A, B, C are written and represents
the control group, Ephedrine and Ondansetron, and then
the syringe containing 2 ml Injections of colorless
solution into the control group: Distilled water in the
Ephedrine group: 10 mg Ephedrine and in the
Ondansetron group: 4 mg of the drug. Assessor and
patient from syringe content and classification Groups do
not know.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical
Sciences

Street address

Azadi Blvd

City

Zanjan

Province

Zanjan

Postal code

4515613113

Approval date

2019-08-03, 1398/05/12

Ethics committee reference number

IR.ZUMS.REC.1398.179

Health conditions studied

1

Description of health condition studied

Hypotension after Spinal Anesthesia

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anesthesia
during labor and delivery

Primary outcomes

1

Description

Hypotension

Timepoint

Blood pressure measurement at the beginning of the
Study and immediately after the Spinal Anesthesia,
every three minutes to 15 minutes and then every five
minutes until the End of the Operation.

Method of measurement

Blood pressure Device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ephedrine Group: Five minutes
before the Spinal Anesthesia, two ml solution containing
10 mg ephedrine is given intravenously.

Category

Treatment - Drugs

2

Description

Intervention group: ondansetron: Five minutes before
spinal anesthesia two ml solution containing 4 mg
ondansetron is injected intravenously.

Category

Treatment - Drugs

3

Description

Control group: Five minutes before spinal anesthesia,
two ml of distilled water is injected intravenously.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Musavi Hospital

Full name of responsible person

Dr. Vahide Rashtchi

Street address

Musavi Hospital, gavazang Road, Zanzan Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

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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

Zanzan 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

Zanzan University of Medical Sciences

Full name of responsible person

Sahar Mahmoodi koli

Position

Anesthetist

Latest degree

Bachelor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zanzan University of Medical Sciences

Full name of responsible person

Dr. Vahide Rashtchi

Position

Assistant Professor

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

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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