Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effects of intravenous ephedrine, of muscular ephedrine and of intradermal ephedrine in preventing hypotension in caesarean section patients with spinal anesthesia

Protocol summary

Summary

This study is a double-blind clinical trial with random allocation between intervention and control groups with a sample size of 96 in executing cesarean section through spinal anesthesia. Inclusion criteria: 20- to 30years old mothers who participate in class 1 and 2 ASA, who do not have a history of high blood pressure. Exclusion criteria: participants in class 3 and 4 ASA; any history of hypertension and pre-eclampsia and eclampsia. The first group, 10 minutes prior to spinal anesthesia, receive 30 mg of muscular ephedrine in the deltoid. In the first group, 10 minutes prior to spinal anesthesia, 10 mg of intradermal ephedrine is injected in the forearm. In the third group, immediately after spinal anesthesia, 20 mg of intravenous ephedrine is injected and in the fourth group 2 ml of normal saline is injected immediately after spinal anesthesia. In addition to the effect of ephedrine injection in intramuscular, intravenous and intradermal ways to prevent hypotension, the present study also measures chills, nausea and vomiting. It is noteworthy that all patients participated in this project with informed consent.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015092824233N1**
Registration date: **2016-01-30, 1394/11/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-30, 1394/11/10

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Vice chancellor for research, Jahrom University of Medical Sciences

Expected recruitment start date

2015-05-15, 1394/02/25

Expected recruitment end date

2016-10-31, 1395/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of intravenous ephedrine, of muscular ephedrine and of intradermal ephedrine in preventing hypotension in caesarean section patients with spinal anesthesia

Public title

Comparing the effects of intravenous ephedrine, of muscular ephedrine and of intradermal ephedrine in preventing hypotension

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 20 to 30years old mothers who participate in class 1 and 2 ASA; tend to have spinal anesthesia; do not have a base systolic blood pressure more than 130 mmHg and less than 90 mmHg; do not have a history of high blood pressure and are consciously willing to participate in the project. Exclusion criteria: participants in class 3 and 4 ASA; patients with cardiovascular disease; people with tachycardia (over 100 beats per minute) and with bradycardia (less than 60 beats per minute); any history of hypertension, diabetes mellitus; patients with thyroid disease, using beta-agonists and beta blockers; preterm delivery; using banned drugs during pregnancy; preeclampsia and pre-eclampsia and eclampsia.
Age
From **20 years** old to **30 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Jahrom University of Medical Sciences
Street address
Jahrom University of Medical Sciences, Motahhari Blvd
City
Jahrom
Postal code
Approval date
2015-05-13, 1394/02/23
Ethics committee reference number
IR.JUMS.REC.1394.006

Health conditions studied

1

Description of health condition studied
Hypotension induced by injection of intravenous ephedrine, of muscular ephedrine and of intradermal ephedrine
ICD-10 code
I95.2
ICD-10 code description
Hypotension due to drugs

Primary outcomes

1

Description
Blood pressure
Timepoint
Every 2.5 minutes to 10 minutes and then until 45 minutes every 5 minutes
Method of measurement
mmHg

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
every 15 minutes
Method of measurement
Scale Alderet

2

Description
Shivering
Timepoint
Every 15 minutes
Method of measurement
Scale rossely & mahajan

Intervention groups

1

Description
In The third group received an intravenous drug, Immediately after the entry of women into the operating room 10 milliliters per kilogram of body weight Ringer will be administered through IV No. 18 for them. Then immediately after spinal anesthesia will be administered to the patient intravenously 20 mg ephedrine.
Category
Treatment - Drugs

2

Description
In The fourth group received a placebo, Immediately after the entry of women into the operating room 10

milliliters per kilogram of body weight Ringer will be administered through IV No. 18 for them. Then 2 ml of saline immediately after spinal anesthesia will be administered to any patient.

Category

Placebo

3

Description

In the second group received intradermal drug, Immediately after the entry of women into the operating room 10 milliliters per kilogram of body weight Ringer will be administered through IV No. 18 for them. Then 10 minutes before spinal anesthesia in the forearm intradermal injection of 10 mg of ephedrine will.

Category

Treatment - Drugs

4

Description

The first group received the drug muscle, Immediately after the entry of women into the operating room 10 milliliters per kilogram of body weight Ringer will be administered through IV No. 18 for them. Then 10 minutes before spinal anesthesia with 30 mg of ephedrine in the deltoid region will receive.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Mohsen Farkhondehfal

Street address

City

Jahrom

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Jahrom University of Medical Sciences

Full name of responsible person

Kavoos Solhjo

Street address

Jahrom University of Medical Sciences, Motahhari Blvd.

City

Jahrom

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Jahrom University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Mohsen Farkhondehfal

Position

Student

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Anesthesiologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty