# 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**

**Name**

Hasan Zabetian

**Name of organization / entity**

Jahrom University of Medical Sciences

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Iran (Islamic Republic of)

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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**

Dr.Hasan Zabetian

**Position**

Anesthesiologist

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## Person responsible for updating data

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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*