

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparing the effect and complications of intravenous Epinephrine and Ephedrine in management of spinal anesthesia hypotension and bradycardia in elective caesarian section

#### Protocol summary

##### Study aim

1. Determining the effects and side effects of intravenous epinephrine and ephedrine in the management of hypotension and bradycardia and determining the effects and side effects of intravenous epinephrine and ephedrine on fetal pH and Apgar score due to spinal cesarean section elective cesarean section

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 126 patients, including 63 patients receiving epinephrine and 63 patients receiving ephedrine

##### Settings and conduct

In the operating room of Kamali Hospital , Intravenous injections of epinephrine or ephedrine measure blood pressure and heart rate every 2 minutes until 20 minutes and then every 5 minutes until 45 minutes. The researcher and patient assessor who analyzed the data both used patient codes

##### Participants/Inclusion and exclusion criteria

Inclusion criteria :Elective cesarean section candidate, consent to participate in the study, pregnant women 20-40 years old in ASA2 class, gestational age 36-40 weeks ,a drop blood pressure more than 20% or systolic blood pressure less than 100 mm Hg Exclusion criteria: Contraindications for spinal anesthesia, Primary blood pressure more than 90/140 mm Hg or heart disease , Sensitivity to the drugs used and Diagnosed diseases of the placenta

##### Intervention groups

Epinephrine injection at a dose of 4 µg bolus in the intervention group or injection of 10 mg intravenous ephedrine at a dose of 10 mg bolus in the control group until the mother reaches systolic blood pressure more than 100 mm Hg

##### Main outcome variables

blood pressure ;heart beat ;Fetal Apgar; Fetal pH .

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201115049395N1**

Registration date: **2020-12-05, 1399/09/15**

Registration timing: **retrospective**

Last update: **2020-12-05, 1399/09/15**

Update count: **0**

##### Registration date

2020-12-05, 1399/09/15

##### Registrant information

##### Name

Fatemeh Moradi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3680 1995

##### Email address

fatiiim73@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-14, 1399/06/24

##### Expected recruitment end date

2020-11-14, 1399/08/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparing the effect and complications of intravenous Epinephrine and Ephedrine in management of spinal anesthesia hypotension and bradycardia in elective caesarian section

## Public title

Comparison of the effect and side effects of intravenous epinephrine and ephedrine in controlling hypotension and heart rate in cesarean section women

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Consent to participate in the study Pregnant women 40-20 years old in ASA2 class Gestational age 40-36 weeks A drop in blood pressure of more than 20% or a decrease in systolic blood pressure of less than 100 mm Hg

### Exclusion criteria:

Contraindications for spinal anesthesia Primary blood pressure more than 90/140 mm Hg or heart disease Diagnosed diseases of the placenta Sensitivity to the drugs used

## Age

From **20 years** old to **40 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **126**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Samples are entered into the study in an accessible manner and randomly assigned to the intervention and control groups using randomization software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The researcher and patient assessor who analyzed the data both used patient codes .Also, the titles of the groups were coded with A and B, but neither of them knew which of the two was the epinephrine group and the control group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Alburz University of Medical Sciences

##### Street address

kamali hospital , kamali st. , shahid beheshti Ave , city of karaj , alburz

##### City

karaj

##### Province

Alborz

##### Postal code

3134877179

#### Approval date

2020-11-14, 1399/08/24

#### Ethics committee reference number

IR.ABZUMS.REC.1399.196

## Health conditions studied

### 1

#### Description of health condition studied

Hypotension and bradycardia following injection of spinal anesthesia

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The rate of hypotension

#### Timepoint

Before injecting spinal anesthesia then every 2 minutes to 20 minutes and then every 5 minutes to 45 minutes

#### Method of measurement

Measurement by monitoring device

### 2

#### Description

Bradycardia

#### Timepoint

Before injecting spinal anesthesia then every 2 minutes to 20 minutes and then every 5 minutes to 45 minutes

#### Method of measurement

Measurement by monitoring device

## Secondary outcomes

### 1

#### Description

Apgar fetus

#### Timepoint

1 minute and 5 minutes after delivery

**Method of measurement**

Apgar scoring form of 10 points

**2**

**Description**

Fetal pH

**Timepoint**

After delivery and umbilical cord incision

**Method of measurement**

By sending a cord blood sample to the laboratory and determining the pH of the fetus

**Intervention groups**

**1**

**Description**

Intervention group : Epinephrine is injected at a dose of 4 micrograms bolus until the mother reaches systolic blood pressure of more than 100 mm Hg

**Category**

Treatment - Other

**2**

**Description**

control group :Intravenous ephedrine at a dose of 10 mg as a bolus until the mother reaches systolic blood pressure more than 100 mm Hg

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

kamali hospital

**Full name of responsible person**

Fatemeh moradi

**Street address**

kamali hospital, kamali st. , Shahid beheshti Ave , Taleghani crossroads

**City**

karaj

**Province**

Alborz

**Postal code**

31344877179

**Phone**

+98 26 3222 2021

**Email**

fatiiiim73@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Nouri Sepehr

**Street address**

Deputy of research and technology , Saffarian Alley , 45 meters from Golshahr , karaj

**City**

karaj

**Province**

Alborz

**Postal code**

3198764653

**Phone**

+98 26 3774 3464

**Email**

Research@abzums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Karaj 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**

Karaj University of Medical Sciences

**Full name of responsible person**

Fatemeh moradi

**Position**

Medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

unit6 , Western A3 block , Imam Reza Complex , Shohada Ave. , Gheibi st. , Javanmard ghasab , Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1845943897

**Phone**

+98 21 3680 1995

**Email**

fatiiiim73@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Fatemeh moradi

**Position**

Medical student

**Latest degree**

A Level or less

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

The study protocol and informed consent form and  
clinical study report and part of the participants' data file  
are shared as the main outcome.

**When the data will become available and for how long**

2 months after printing the results

**To whom data/document is available**

All

**Under which criteria data/document could be used**

No conditions are required.

**From where data/document is obtainable**

Fatemeh moradi - fatiiiim73@gmail.com

**What processes are involved for a request to access data/document**

Information will be available within 2 weeks after sending  
email and authentication.

**Comments**