Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

fatiiiim73@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

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1845943897

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+98 21 3680 1995

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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

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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