

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Comparison of Intravenous bolus Phenylephrine and Ephedrine for prevention of postspinal Hypotension during Cesarean section.

Protocol summary

Study aim

Comparison of intravenous injection of phenylephrine and ephedrine in preventing post spinal hypotension in cesarean section

Design

80 patients were randomly assigned to a double blind randomized phase 4 clinical trial. They are randomly placed in 4 blocks and enter into one of two ephedrine (A) and phenylephrine (B) groups.

Settings and conduct

After spinal anesthesia in candidates for C/S in Fatemieh hospital of Hamedan, they are placed in a supine position and in one of two groups A (10 mg ephedrine) or B (100 µg phenylephrine) .Both medicines are prepared by an anesthetist nurse who does not have information from the groups in syringes of the same shape and volume, and injected intravenously, in which anesthetist and patient are not familiar with the type of medication prescribed

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18 to 45; healthy and candidates for C/S under spinal anesthesia. Exclusion criteria: Cardiac disease; Renal disease; Hypertension; Diabetes; Eclampsia and pre-eclampsia; Multiple pregnancy; Candidates for emergency C/S and spinal anesthesia contraindications.

Intervention groups

Patients were restored to supine position after spinal anesthesia and in group A 10 mg ephedrine and group B 100 microgram phenylephrine, is prepared with the same shape and volume, by an anesthetist nurse and is injected intravenously.

Main outcome variables

Systolic; Diastolic blood pressure; Mean arterial pressure; heart rate and SPO2 in 0, 2, 4, 6, 8, 10, 15, 20, 25, 30, 40, 50, 60 minutes; nausea and vomiting; first and fifth minutes Apgar score and consum ephedrine and atropine are registered.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N8**

Registration date: **2018-06-23, 1397/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-23, 1397/04/02**

Update count: **0**

Registration date

2018-06-23, 1397/04/02

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

Email address

manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Intravenous bolus Phenylephrine and Ephedrine for prevention of postspinal Hypotension during Cesarean section.

Public title

Determination of effective drug in prevention of post spinal hypotension in C/S

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA CLASS 1(Healthy Patients) 18-45 aged pregnant patients for C/S

Exclusion criteria:

Cardiac disease Renal disease History of hypertensive disease Diabetes Eclampsia &pre eclampsia Multiple pregnancy C/S for meconium or fetal distress Contraindications for spinal anesthesia

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the randomization method is used as a 4-blocks. In this way, according to the sample size, 20 blocks of four are identified, and in each of these blocks of four, two of each group will be written in the form of letters A or B. This means that two A and two B are written in each block, although the order of the writing of the four letters A and B will be different in each block.

The periodic numbers table will then be used to determine the order of block selection.

Blinding (investigator's opinion)

Double blinded

Blinding description

Ephedrine (10 mg) and phenylephrine (100 µg) in the same volumes (1 ml) are prepared in the same syringes by the anesthetist nurse according to the list of patients entered into the study (based on the four blocks) and then administered intravenously after spinal anesthesia. . Therefore, the anesthetist, the patient and the person evaluating the outcome (anesthetist) are not familiar with the type of prescribed medication

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan university of Medical Sciences

Street address

Fahmide Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2017-11-25, 1396/09/04

Ethics committee reference number

IR.UMSHA.REC.1396.580

Health conditions studied

1

Description of health condition studied

post spinal anaesthesia hypotension

ICD-10 code

O74.6

ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Minutes of 0,2, 4, 6, 8, 10,15, 20, 25, 30, 40, 50 and 60 after spinal anesthesia

Method of measurement

Automatic non-invasive blood pressure device

2

Description

Diastolic blood pressure

Timepoint

Minutes of 0,2, 4, 6, 8, 10,15, 20, 25, 30, 40, 50 and 60 after spinal anesthesia

Method of measurement

Automatic non-invasive blood pressure device

3

Description

Mean arterial pressure

Timepoint

Minutes of 0,2, 4, 6, 8, 10,15, 20, 25, 30, 40, 50 and 60 after spinal anesthesia

Method of measurement

Automatic non-invasive blood pressure device

Secondary outcomes

1

Description

Heart rate

Timepoint

Minutes of 0,2, 4, 6, 8, 10,15, 20, 25, 30, 40, 50 and 60 after spinal anesthesia.

Method of measurement

Pulse oximetry device

2

Description

Arterial oxygen saturation

Timepoint

Minutes of 0,2, 4, 6, 8, 10,15, 20, 25, 30, 40, 50 and 60 after spinal anesthesia.

Method of measurement

Pulse oximetry device

3

Description

Nausea and vomiting

Timepoint

During surgery

Method of measurement

Observation

4

Description

Apgar Score of neonate

Timepoint

The first and fifth minutes after birth

Method of measurement

Examination and calculation on Apgar score

5

Description

The amount of ephedrine have been consumed

Timepoint

during surgery

Method of measurement

The amount of ephedrine have been consumed by mg

6

Description

The amount of atropine have been consumed

Timepoint

during surgery

Method of measurement

The amount of atropine have been consumed by mg

Intervention groups

1

Description

First intervention group : In this group immediately after the spinal anesthesia, 10 mg (1ml) of ephedrine which is a vasoconstrictor for prevention of hypotension is injected intravenously.

Category

Prevention

2

Description

Second intervention group : In this group immediately after the spinal anesthesia, 100 ug (1ml) of ephedrine which is a vasoconstrictor for prevention of hypotension is injected intravenously.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

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Fatemieh Hospital, Pasdaran Street.

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Hamedan University of Medical Sciences, vice chancellor of research
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
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Position
Associate professor
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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