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 emegency 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 Manuchehrian
Name of organization / entity
Hamedan University of Medical Sciences
Country
Iran (Islamic Republic of)
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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 vaoconstrictor for prevetion 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 vaoconstrictor for prevetion 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

Street address

Fatemieh Hospital, Pasdaran Street.

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Email

hp.fatemieh@gmail.com

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

Street address

Fahmieh Street, Hamadan university of medical sciences

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Web page address

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
Hamedan University of Medical Sciences

Full name of responsible person
Nahid Manouchehrian

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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