Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of intravenous bolous of Nor epinephrine and Ephedrine in prevention of post spinal hypotension in cesarean section

Protocol summary

Study aim
Comparison effect of intravenous bolous of Nor epinephrine and Ephedrine in prevention of post spinal hypotension in cesarean section

Design
The aim of this study was to compare the effect of intravenous bolous of Nor epinephrine and Ephedrine in prevention of post spinal hypotension in cesarean section.In this double-blind study, 50 patients aged 18 to 46 years old with cesarean delivery at Fatemieh Hospital of Hamedan were randomly assigned to receive 5 µg of norepinephrine (group A) and 10 mg of ephedrine (group B) after being informed consent.Patients who declare that they are not collaborating or have sensitivity to medications used. will be excluded

Settings and conduct
Fatemieh Hospital of Hamadan

Participants/Inclusion and exclusion criteria
Satisfaction to participate in the project; Pregnant women aged 18 to 46; Pregnant women who underwent cesarean section under spinal anesthesia

Intervention groups
Patients were randomly assigned to two groups treated with 5 mcg norepinephrine (Group A) and 10 mg of ephedrine (Group B).

Main outcome variables
Hypotension

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120915010841N17**
Registration date: **2019-05-17, 1398/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-17, 1398/02/27**
Update count: **0**

Registration date
2019-05-17, 1398/02/27

Registrant information

Name
Nahid Manuchehrian

Name of organization / entity
Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-15, 1398/02/25

Expected recruitment end date
2020-05-14, 1399/02/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of intravenous bolous of Nor epinephrine and Ephedrine in prevention of post spinal hypotension in cesarean section

Public title
intravenous bolous of Nor epinephrine and Ephedrine in prevention of post spinal hypotension in cesarean section

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the project Pregnant women aged 18 to 46 Pregnant women who underwent cesarean section under spinal anesthesia

Exclusion criteria:

sensitivity to medications used Patients who have failed spinal anesthesia and undergo general anesthesia Lung disease, heart disease, asthma, fever, hypertension, preeclampsia and eclampsia, cardiac arrhythmia

Age

From **18 years** old to **46 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Block Randomization is used to randomize blocks as 5 blocks. we provide five paper sheets . We write five letters A and on five other sheets of letter B. We mix the papers together and put them in the drawer of the table.With each of the qualified patients, one of the papers is taken out randomly and will be assigned to one of the two groups A (norepinephrine) and B (ephedrine). Then, for ten subsequent patients, the paper is returned to the bag again, and this process is repeated until the end of the sample volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

In both groups A and B, medications will be prescribed two minutes before the extubation of the chip. In order to prevent the medication being detectable for patients and investigators, they are prepared and injected into syringes of the same size and shape and on the adhesives A and B by the anesthetist. Since drugs are prescribed and prescribed by an anesthetist, the clinician will not be aware of the type of prescribed medication that will measure and record the outcome of the study.

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 Science

Street address

Fahmide Street

City

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Postal code

6517838678

Approval date

2019-02-23, 1397/12/04

Ethics committee reference number

IR.UMSHA.REC.1397.867

Health conditions studied

1

Description of health condition studied

Spinal anesthesia in cesarean section

ICD-10 code

Z38.01

ICD-10 code description

Single liveborn infant, delivered by cesarean

Primary outcomes

1

Description

hypotension

Timepoint

Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, then every 10 minutes until the end of the surgery

Method of measurement

Non-invasive blood pressure

Secondary outcomes

1

Description

Nausea & vomiting

Timepoint

after delivery

Method of measurement

Observation

2

Description

new born Apgar

Timepoint

1&5 minutes after delivery

Method of measurement

Apgar Score

3

Description
Headache
Timepoint
after delivery
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: 5 µg of norepinephrine is injected immediately after spinal anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group: The 10 mg ephedrine is injected immediately after spinal anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Nahid Manouchehrian, Anesthesiologist, Assistant Professor of Hamadan University Of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Nahid Manouchehrian
Position
Associate professor of Hamadan University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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